

UNITED STATES DISTRICT COURT  
FOR THE DISTRICT OF MASSACHUSETTS

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IN RE PHARMACEUTICAL INDUSTRY )  
AVERAGE WHOLESALE PRICE ) MDL NO. 1456  
LITIGATION )  
THIS DOCUMENT RELATES TO: ) Civil Action No. 01-12257-PBS  
*The City of New York v. Abbott* )  
*Laboratories, Inc., et al.* )  
S.D.N.Y. Case No. 04-CV-06054 )  
*County of Albany v. Abbott Laboratories,* )  
*Inc., et al.* )  
N.D.N.Y. Case No. 05-CV-0425 )  
*County of Allegany v. Abbott Laboratories,* )  
*Inc., et al.* )  
W.D.N.Y. Case No. 05-CV-0236 )  
*County of Broome v. Abbott Laboratories,* )  
*Inc., et al.* )  
N.D.N.Y. Case No. 05-CV-0456 )  
*County of Cattaraugus v. Abbott* )  
*Laboratories, Inc., et al.* )  
W.D.N.Y. Case No. 05-CV-0256 )  
*County of Cayuga v. Abbott Laboratories,* )  
*Inc., et al.* )  
N.D.N.Y. Case No. 05-CV-0423 )  
*County of Chautauqua v. Abbott* )  
*Laboratories, Inc., et al.* )  
W.D.N.Y. Case No. 05-CV-0214 )  
*County of Chemung v. Abbott* )  
*Laboratories, Inc., et al.* )  
W.D.N.Y. Case No. 05-CV-6744 )  
*County of Chenango v. Abbott* )  
*Laboratories, Inc., et al.* )  
N.D.N.Y. Case No. 05-CV-0354 )  
*County of Columbia v. Abbott* )  
*Laboratories, Inc., et al.* )  
N.D.N.Y. Case No. 05-CV-0867 )  
*County of Cortland v. Abbott Laboratories,* )  
*Inc., et al.* )  
N.D.N.Y. Case No. 05-CV-0881 )  
*County of Dutchess v. Abbott Laboratories,* )

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<i>Inc., et al.</i>	)
S.D.N.Y. Case No. 05-CV-6458	)
<i>County of Essex v. Abbott Laboratories,</i>	)
<i>Inc., et al.</i>	)
N.D.N.Y. Case No. 05-CV-0878	)
<i>County of Fulton v. Abbott Laboratories,</i>	)
<i>Inc., et al.</i>	)
N.D.N.Y. Case No. 05-CV-0519	)
<i>County of Genesee v. Abbott Laboratories,</i>	)
<i>Inc., et al.</i>	)
W.D.N.Y. Case No. 05-CV-00267	)
<i>County of Greene v. Abbott Laboratories,</i>	)
<i>Inc., et al.</i>	)
N.D.N.Y. Case No. 05-CV-0474	)
<i>County of Herkimer v. Abbott</i>	)
<i>Laboratories, Inc., et al.</i>	)
N.D.N.Y. Case No. 05-CV-00415	)
<i>County of Jefferson v. Abbott Laboratories,</i>	)
<i>Inc., et al.</i>	)
N.D.N.Y. Case No. 05-CV-0715	)
<i>County of Lewis v. Abbott Laboratories,</i>	)
<i>Inc., et al.</i>	)
N.D.N.Y. Case No. 05-CV-0839	)
<i>County of Madison v. Abbott Laboratories,</i>	)
<i>Inc., et al.</i>	)
N.D.N.Y. Case No. 05-CV-00714	)
<i>County of Monroe v. Abbott Laboratories,</i>	)
<i>Inc., et al.</i>	)
W.D.N.Y. Case No. 05-CV-6148	)
<i>County of Nassau v. Abbott Laboratories,</i>	)
<i>Inc., et al.</i>	)
E.D.N.Y. Case No. 04-CV-05126	)
<i>County of Niagara v. Abbott Laboratories,</i>	)
<i>Inc., et al.</i>	)
W.D.N.Y. Case No. 05-CV-06296	)
<i>County of Oneida v. Abbott Laboratories,</i>	)
<i>Inc., et al.</i>	)
N.D.N.Y. Case No. 05-CV-0489	)
<i>County of Onondaga v. Abbott</i>	)
<i>Laboratories, Inc., et al.</i>	)
N.D.N.Y. Case No. 05-CV-0088	)
<i>County of Ontario v. Abbott Laboratories,</i>	)
<i>Inc., et al.</i>	)
W.D.N.Y. Case No. 05-CV-6373	)
<i>County of Orange v. Abbott Laboratories,</i>	)
<i>Inc., et al.</i>	)

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S.D.N.Y. Case No. 07-CV-2777	)
<i>County of Orleans v. Abbott Laboratories,</i>	)
<i>Inc., et al.</i>	)
W.D.N.Y. Case No. 05-CV-6371	)
<i>County of Putnam v. Abbott Laboratories,</i>	)
<i>Inc., et al.</i>	)
S.D.N.Y. Case No. 05-CV-04740	)
<i>County of Rensselaer v. Abbott</i>	)
<i>Laboratories, Inc., et al.</i>	)
N.D.N.Y. Case No. 05-CV-00422	)
<i>County of Rockland v. Abbott</i>	)
<i>Laboratories, Inc., et al.</i>	)
S.D.N.Y. Case No. 03-CV-7055	)
<i>County of Schuyler v. Abbott Laboratories,</i>	)
<i>Inc., et al.</i>	)
W.D.N.Y. Case No. 05-CV-6387	)
<i>County of Seneca v. Abbott Laboratories,</i>	)
<i>Inc., et al.</i>	)
W.D.N.Y. Case No. 05-CV-6370	)
<i>County of St. Lawrence v. Abbott</i>	)
<i>Laboratories, Inc., et al.</i>	)
N.D.N.Y. Case No. 05-CV-0479	)
<i>County of Saratoga v. Abbott Laboratories,</i>	)
<i>Inc., et al.</i>	)
N.D.N.Y. Case No. 05-CV-0478	)
<i>County of Steuben v. Abbott Laboratories,</i>	)
<i>Inc., et al.</i>	)
W.D.N.Y. Case No. 05-CV-6223	)
<i>County of Suffolk v. Abbott Laboratories,</i>	)
<i>Inc., et al.</i>	)
E.D.N.Y. Case No. 03-CV-12257	)
<i>County of Tompkins v. Abbott</i>	)
<i>Laboratories, Inc., et al.</i>	)
N.D.N.Y. Case No. 05-CV-0397	)
<i>County of Ulster v. Abbott Laboratories,</i>	)
<i>Inc., et al.</i>	)
N.D.N.Y. Case No. 06-CV-0123	)
<i>County of Warren v. Abbott Laboratories,</i>	)
<i>Inc., et al.</i>	)
N.D.N.Y. Case No. 05-CV-0468	)
<i>County of Washington v. Abbott</i>	)
<i>Laboratories, Inc., et al.</i>	)
N.D.N.Y. Case No. 05-CV-0408	)
<i>County of Wayne v. Abbott Laboratories,</i>	)
<i>Inc., et al.</i>	)
W.D.N.Y. Case No. 05-CV-06138	)

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*County of Westchester v. Abbott* )  
*Laboratories, Inc., et al.* )  
S.D.N.Y. Case No. 03-CV-6178 )  
*County of Wyoming v. Abbott* )  
*Laboratories, Inc., et al.* )  
W.D.N.Y. Case No. 05-CV-6379 )  
*County of Yates v. Abbott Laboratories,* )  
*Inc., et al.* )  
W.D.N.Y. Case No. 05-CV-06172 )  
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## **Affidavit of Dr. Sumanth Addanki**

**June 30, 2009**

## I. Introduction

### A. Qualifications and Assignment

1. I am an economist and a Senior Vice President at NERA Economic Consulting (NERA).

I hold a Ph.D. degree in economics from Harvard University and have specialized in the study of industrial organization. My qualifications are summarized in Exhibit 1 and were set out more fully in the Report and two affidavits that I rendered in this matter in March, May and June of this year, respectively.<sup>1</sup>

2. Counsel for the defendants in this matter asked me to review and respond to the declaration of Ms. Gaston in which she discusses the approach that she followed in setting Federal Upper Limits (“FULs”).<sup>2</sup>

### B. Information Relied Upon

3. This report is based on my professional training and experience, including my experience working in other cases involving allegations of Average Wholesale Price (“AWP”) and Wholesale Acquisition Cost (“WAC”) manipulation. My staff at NERA and I have reviewed various materials, including data from pricing compendia, public documents and court filings. A list of the materials relied upon in preparing this affidavit is attached as Exhibit 2.<sup>3</sup>

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<sup>1</sup> See Expert Report of Dr. Sumanth Addanki, In re: Pharmaceutical Industry Average Wholesale Price Litigation relating to The City of New York et al. v. Abbott Laboratories, Inc., et al., March 18, 2009 (“Addanki Report”); Affidavit of Dr. Sumanth Addanki, In re: Pharmaceutical Industry Average Wholesale Price Litigation relating to The City of New York et al. v. Abbott Laboratories, Inc., et al., May 15, 2009; Affidavit of Dr. Sumanth Addanki, In re: Pharmaceutical Industry Average Wholesale Price Litigation relating to The City of New York et al. v. Abbott Laboratories, Inc., et al., June 15, 2009.

<sup>2</sup> Declaration of Susan E. Gaston, In re: Pharmaceutical Industry Average Wholesale Price Litigation relating to The City of New York et al. v. Abbott Laboratories, Inc., et al., June 15, 2009 (“Gaston Declaration”).

<sup>3</sup> For completeness, this exhibit also includes materials relied upon in preparing my earlier report and affidavits.

### C. Summary of Conclusions

4. Ms. Gaston states that it was her practice to base the FUL on the lowest WAC for which the resulting FUL would be higher than at least three WACs that were “valid and ... nationally available”, including the one used to set the FUL.<sup>4</sup> Thus, Ms. Gaston’s declaration confirms that CMS did not follow the regulation specifying how FULs would be set but, rather, exercised substantial discretion in setting the FULs, in order to ensure access.<sup>5</sup>
5. I have reviewed the FULs at issue in this matter in light of the rule of thumb that Ms. Gaston sets forth (i.e., the principle that at least three WACs were to be lower than the FUL). I find that, given the published prices available on which FULs could have been based, the FULs actually set *cannot* for the most part be predicted by using this alternative rule. Overwhelmingly, the FULs actually set were either “too high” (i.e., lower WACs existed that could have been used to set a FUL that would have satisfied the “three WACs lower” condition) or “too low” (i.e., there were *not* three WACs below the FUL) or not based on a valid published price. Only 6 out of the 31 FULs were “just right,” being based on a valid published price and neither “too high” nor “too low” under Ms. Gaston’s rule, nor based on an invalid price.

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<sup>4</sup> Gaston Declaration, Paragraphs 4-5 (“still valid and ...nationally available” ...“If the lowest WAC resulted in a FUL that was higher than at least three published WACs (including the WAC used to calculate the FUL), I would use that WAC to set the FUL. However, if the resulting FUL was not higher than at least three published WACs, I might use the next higher WAC.”)

<sup>5</sup> Gaston Declaration, Paragraphs 5 (“To the extent I exercised this discretion when setting a FUL, I did so in order to ensure access while also achieving cost savings for the Medicaid program as required by 42 C.F.R. § 447.332.”)

## II. Ms. Gaston's Declaration

6. I compared Ms. Gaston's description of setting the FUL on the lowest WAC that produces a FUL with at least three WACs below it with the 31 FULs at issue in this matter. Of the 23 FULs for which I found the lowest published price was not used to set the FUL (see exhibit 3 of my report), 20 of these FULs could still have had a lower FUL even if it should have been based on a lower published WAC and still had at least three WACs below it.<sup>6</sup> See Exhibit 3. In addition, there are four FULs that were set where there were not at least three lower WACs. See Exhibit 4. Thus, 24 FULs of the 31 at issue here, or roughly 77 percent, were either set too high or too low, if the "rule" were to have "at least three WACs" below the FUL. In addition, as I noted in my report, the FUL for cefadroxil set in October 1996 was apparently based on an invalid price. See Exhibit 5 for a summary. So, only 6 of the 31 FULs, or 19 percent, are consistent with Ms. Gaston's rule.
  
7. In her declaration, Ms. Gaston states that she would not consider prices if she "learned that the product was not nationally available", but does not define this concept.<sup>7</sup> However, lower-priced NDCs that were passed over by CMS had shares of national CMS reimbursement that were as high or higher than that of the NDC apparently used to set the FUL. See Exhibits 6 through 11. In setting the FUL for clonazepam in January 2000, CMS passed over several lower WACs, one for an NDC with nearly 50 percent of the national Medicaid reimbursement. See Exhibit 6. Much the same happened in the setting of the FUL for clonazepam in April 2001. See Exhibit 7. In April 2001, CMS also set a FUL for metoprolol, where there were several lower published prices available

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<sup>6</sup> Moreover, two of these FULs also appear to have been set based on a Direct Price ("DP"), and not a WAC.

<sup>7</sup> Gaston Declaration, Paragraph 4.

with shares similar to or greater than the NDC on which the FUL was based.<sup>8</sup> See Exhibit 8. Another FUL set in April 2001 was set for cefadroxil, where, again, there was at least one lower WAC that accounted for a substantial portion of the market. See Exhibit 9. In setting the FUL for albuterol 0.083% in April 2001, nine NDCs with lower WACs were passed over, some with shares over 10 percent. See Exhibit 10. In setting the FUL for the albuterol inhaler in June 1997, CMS passed over an NDC with more than a 20 percent share of national Medicaid reimbursement. See Exhibit 11.



Sumanth Addanki

6-30-09

Date

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<sup>8</sup> Ms. Gaston testified that she may have eliminated Caraco's NDC because it was either "too low" or not available nationwide (Deposition of Sue Gaston, March 19, 2008, p. 429). However, if CMS reimbursement is any guide, Caraco was missing from only a few states' reimbursements, not unlike the two NDCs on which the FUL was apparently based. In 2001, Caraco was not included in the reimbursement for Alaska, Colorado, Idaho, New Hampshire, Rhode Island, Utah, and Washington; URL was not included in the reimbursement for Alaska, Delaware, Hawaii, Idaho, Mississippi, New Hampshire, and Vermont; and Mutual was not included in the state reimbursement for Washington, DC and Delaware.

# NERA

Economic Consulting

**Sumanth Addanki**  
Senior Vice President

National Economic Research Associates, Inc.  
50 Main Street  
White Plains, New York 10606  
+1 914 448 4000 Fax +1 914 448 4040  
Direct dial: +1 914 448 4060  
[sumanth.addanki@nera.com](mailto:sumanth.addanki@nera.com)  
[www.nera.com](http://www.nera.com)

## **SUMANTH ADDANKI** **SENIOR VICE PRESIDENT**

### **Education**

**Harvard University**  
Ph.D., Economics, 1986

**Birla Institute of Technology and Science, India**  
M.A. (Hons.), Economics, 1980

### **Professional Experience**

1986-	<b>NERA Economic Consulting</b> Senior Vice President (current position)
1997	<b>New York University, Robert F. Wagner Graduate School of Public Service</b> Adjunct Assistant Professor of Public and Health Administration
1981-1986	<b>National Bureau of Economic Research Inc.</b> Research Associate and Computer Manager
1981-1985	<b>Harvard University</b> Instructor in Economics, Teaching Fellow, and Assistant Head Tutor
1980	<b>National Council of Applied Economic Research, India</b> Research Associate

### **Honors and Professional Activities**

Associate Editor, *Antitrust Magazine*, 2001 - 2002

Vice Chair, Economics Committee at Antitrust Section of ABA, 1999 - 2000

Danforth Center Award for Excellence in Teaching, Harvard University, 1983

## Testimony (2005 – 2009)

*Mitsubishi Chemical Corporation, Mitsubishi Tanabe Pharma Corporation, Encysive Pharmaceuticals Inc., Glaxo Group Limited, SmithKline Beecham plc, and SmithKline Beecham Corp., d/b/a GlaxoSmithKline v. Barr Laboratories, Inc. and Pliva-Hrvatska d.o.o., United States District Court for the Southern District of New York, CA No. 07 CV 11614 (Deposition Testimony) June 18, 19, 2009.*

*In re Pharmaceutical Industry Average Wholesale Price Litigation: The City of New York v. Abbott Laboratories, Inc., et al., United States District Court for the District of Massachusetts, MDL No. 1456, CA No. 01-12257-PBS (Deposition Testimony) November 2008 and April 2009*

*State of Missouri, ex rel. Jeremiah W. (Jay) Nixon, Attorney General and Missouri Department of Social Services, Division of Medical Services v. Dey, Inc., et al and Warrick Pharmaceuticals Corporation, Schering-Plough Corporation, Schering Corporation, In the Circuit Court of the City of St. Louis State of Missouri, Case No. 054-1216 Division: 2. October 2008*

*State of Wisconsin v. Amgen, Inc., Abbott Laboratories, AstraZeneca Pharmaceuticals, LP, AstraZeneca, LP, Aventis Pharmaceuticals, Inc. Baxter Healthcare Corporation, Ben Venue Laboratories, Inc. et al., The Circuit Court for Dane County in the State of Wisconsin, Case No. 04-CV-1709 (Deposition Testimony) May 2008*

*The Commonwealth of Massachusetts v. Mylan Laboratories, Inc. IVAX Corporation, Warrick Pharmaceutical Corporation, Watson Pharmaceuticals, Inc. Schein Pharmaceutical, Inc., Teva Pharmaceuticals USA, Inc., PAR Pharmaceutical, Inc., Purepac Pharmaceutical Co, and Roxane Laboratories, Inc., U.S. District for the District of Massachusetts, Civil Action No. 03-11865-PBS (Deposition Testimony). April 2008*

*Discover Financial Services, et al. v. Visa U.S.A. Inc., et al., U.S. District Court for the Southern District of New York, Civil Action No 04-CF-7844 (BSJ) (Deposition Testimony). December 2007.*

*State of Alabama v. Abbott Laboratories, Inc., et al., In the Circuit Court of Montgomery County, Alabama, CV-05-219 (Deposition Testimony). November 2007.*

*Dynax Corporation v. Chemguard, Inc., U.S. District Court for the Southern District of New York, Index: 06-CIV-5143 (CM)(ECF CASE) (Deposition Testimony). June 2007*

*State of Colorado, et al. v. Warner Chilcott Holdings Company III, Ltd, et al., U.S. District Court for the District of Columbia, Civil Action No 1:05CV02182 (CKK) (Deposition Testimony). August 2007*

*Novartis Corporation, Novartis Pharmaceuticals Corporation, and Novartis International AG v. Teva Pharmaceuticals USA, Inc., U.S. District Court for the District of New Jersey, Civil Action Nos. 04-4473 and 06-1130 (HAA)(MF) (Deposition Testimony). February 2007*

*In re Pharmaceutical Industry Average Wholesale Price Litigation (MDL 1456)*, U.S. District Court for the District of Massachusetts, Civil Action No. 01-12257-PBS. December 2006

*Briant Chun-Hoon and Carlo Guglielmino v. McKee Foods Corporation, a Tennessee Corporation; and Does 1 through 100, inclusive*, U.S. District Court for the Northern District of California, Case No. C05-00620 VRW (Deposition Testimony). March 2006

*XIotech Corporation v. Compellent Technologies, Inc., Michael Markovich, Russell B. Taddiken, Scott A. Winslow, Kristofer M. Zuber*, District Court for the State of Minnesota, Fourth Judicial District, Court File No.: 04-5065 (Deposition Testimony). March 2006

*Medtronic Minimed, Inc., v. Smiths Medical MD, Inc.*, U. S. District Court for the District of Delaware, Civil Action No. 03-776-KAJ (Deposition Testimony). February 2006

## Papers and Publications (1999 – 2009)

“Patent Settlement Agreements” with Alan J. Daskin, Chapter 85, Volume 3, in *Issues in Competition Law and Policy*, published by American Bar Association, Section of Antitrust Law, August, 2008.

“Who Defines the Relevant Market—The Core Customer or Marginal One?” with Alan Daskin, *Antitrust Insights*, National Economic Research Associates, Inc., Summer 2008.

“*Schering-Plough* and the Antitrust Analysis of Patent Settlement Agreements in Pharmaceutical Markets,” *Antitrust Insights*, National Economic Research Associates, Inc., 2005 and published in *Economics of Antitrust: Complex Issues in a Dynamic Economy*, Chapter 4, May 2007.

“Economists Lend Insight Into Antitrust Risk,” *IFLR (International Financial Law Review), Mergers and Acquisitions* 2004, 2004.

“Market Definitions Using Econometrics: An Apparent Paradox Explained,” *Antitrust Insights*, National Economic Research Associates, Inc., 2001.

“Presenting Complex Technical and Economic Evidence: Lessons From The Trenches,” *Antitrust and Intellectual Property: The Crossroads*, American Bar Association, 2000.

June 2009

## Exhibit 2

### Case Materials

New York Counties v. Abbott Laboratories, Inc., et al. Revised First Amended Consolidated Complaint. October 5, 2007 (including Exhibit B).

Rule 26 Statement of Harris L. Devor, In re: Pharmaceutical Industry Average Wholesale Price Litigation relating to The City of New York, et al. v. Abbott Laboratories, Inc., et al. September 30, 2008.

Declaration of Susan E. Gaston, In re: Pharmaceutical Industry Average Wholesale Price Litigation relating to The City of New York, et al. v. Abbott Laboratories, Inc., et al. June 15, 2009.

Depositions of Harris Devor and exhibits.

Depositions of Sue Gaston and exhibits.

Deposition of Gail Sexton and exhibits.

### Data

"Comprehensive Price History File." 2007 Wolters Kluwer Health (Medispan).

First DataBank (Alabama Production) Data and *NDDF (National Drug Data File)™ Documentation Manual* (Rev. April 2000).

Medicaid State Drug Utilization Data including "Definitions for State Drug Utilization Data Specifications", Centers for Medicare & Medicaid Services.

Medispan Inactive Dates. 2007 Wolters Kluwer Health (Medispan).

Mr. Devor's Electronic Work Files and Exhibits.

Red Book Advanced Data and *Red Book™ Drug Products and Pricing Developer's Guide Advanced* (January 2008).

### Public Knowledge Documents

Alpert, Bill. "Hooked on Drugs: Why Do Insurers Pay Such Outrageous Prices For Pharmaceuticals?" *Barron's*, June 10, 1996.

American Society of Clinical Oncology. *Reform of the Medicare Payment Methods for Cancer Chemotherapy*. May 2001.

<http://www.asco.org/asco/downloads/MedicarePaymentReformASCOWhitePaper.pdf>.

Congressional Budget Office. *How Increased Competition from Generic Drugs has Affected Prices and Returns in the Pharmaceutical Industry*. July 1998.

<http://www.cbo.gov/ftpdoc.cfm?index=655&type=0&sequence=1>.

Congressional Budget Office. *How the Medicaid Rebate on Prescription Drugs Affects Pricing in the Pharmaceutical Industry*. January 1996. <http://www.cbo.gov/ftpdoc.cfm?index=4750>.

Congressional Budget Office. *Medicaid's Reimbursements to Pharmacies for Prescription Drugs*. December 2004. <http://www.cbo.gov/showdoc.cfm?index=6038&sequence=1>.

Congressional Budget Office. *Prices for Brand-Name Drugs Under Selected Federal Programs*. June 2005. <http://www.cbo.gov/ftpdocs/64xx/doc6481/06-16-PrescriptDrug.pdf>.

Congressional Budget Office. *The Rebate Medicaid Receives on Brand-Name Prescription Drugs*. June 21, 2005. <http://www.cbo.gov/ftpdocs/64xx/doc6493/06-21-MedicaidRebate.pdf>.

Department of Health and Human Services, Office of Inspector General. *Addition of Qualified Drugs to the Medicaid Federal Upper Limit List*. December 2004. (OEI-03-04-00320).

Department of Health and Human Services, Office of Inspector General. *Are Medicare Allowances for Albuterol Sulfate Reasonable?* August 1998. (OEI-03-97-00292).

Department of Health and Human Services, Office of Inspector General. *Comparing Drug Reimbursement: Medicare and Department of Veterans Affairs*. November 1998. (OEI-03-97-00293).

Department of Health and Human Services, Office of Inspector General. *A Comparison of Albuterol Sulfate Prices*. June 1996. (OEI-03-94-00392).

Department of Health and Human Services, Office of Inspector General. *Cost of Dialysis-Related Drugs*. October 1992. (A-01-91-00526).

Department of Health and Human Services, Office of Inspector General. *Deficit Reduction Act of 2005: Impact on the Medicaid Federal Upper Limit Program*. June 2007. (OEI-03-06-00400).

Department of Health and Human Services, Office of Inspector General. *Determining Average Manufacturer Prices for Prescription Drugs Under the Deficit Reduction Act of 2005*. May 2006. (A-06-06-00063).

Department of Health and Human Services, Office of Inspector General. *Excessive Medicare Payments for Prescription Drugs*. December 1997. (OEI-03-97-00290).

Department of Health and Human Services, Office of Inspector General. *Excessive Medicare Reimbursement for Albuterol*. March 2002. (OEI-03-01-00410).

Department of Health and Human Services, Office of Inspector General. *The Impact of High-Priced*

*Generic Drugs on Medicare and Medicaid.* July 1998. (OEI-03-97-00510).

Department of Health and Human Services, Office of Inspector General. *Infusion Therapy Services Provided in Skilled Nursing Facilities.* December 1999. (A-06-99-00058).

Department of Health and Human Services, Office of Inspector General. *Medicaid Pharmacy – Actual Acquisition Cost of Brand Name Prescription Drug Products.* August 2001. (A-06-00-00023).

Department of Health and Human Services, Office of Inspector General. *Medicaid Pharmacy – Actual Acquisition Cost of Generic Prescription Drug Products.* August 1997. (A-06-97-00011).

Department of Health and Human Services, Office of Inspector General. *Medicaid Pharmacy – Actual Acquisition Cost of Generic Prescription Drug Products.* March 2002. (A-06-01-00053).

Department of Health and Human Services, Office of Inspector General. *Medicaid Pharmacy – Actual Acquisition Cost of Prescription Drug Products for Brand Name Drugs.* April 1997. (A-06-96-00030).

Department of Health and Human Services, Office of Inspector General. *Medicaid Pharmacy – Additional Analyses of the Actual Acquisition Cost of Prescription Drug Products.* September 2002. (A-06-02-00041).

Department of Health and Human Services, Office of Inspector General. *Medicare Payments for Nebulizer Drugs.* February 1996. (OEI-03-94-00390).

Department of Health and Human Services, Office of Inspector General. *Medicare Reimbursement of Albuterol.* June 2000. (OEI-03-00-00311).

Department of Health and Human Services, Office of Inspector General. *Medicare Reimbursement of Prescription Drugs.* January 2001. (OEI-03-00-00310).

Department of Health and Human Services, Office of Inspector General. *Physicians' Costs for Chemotherapy Drugs.* November 1992. (A-02-91-01049).

Department of Health and Human Services, Office of Inspector General. *Review of Pharmacy Acquisition Costs for Drugs Reimbursed Under the Medicaid Prescription Drug Program of the California Department of Health Services.* May 1996. (A-06-95-00062).

Department of Health and Human Services, Office of Inspector General. *Review of Pharmacy Acquisition Costs for Drugs Reimbursed Under the Medicaid Prescription Drug Program of the Florida Agency for Health Care Administration.* February 2002. (A-06-01-00002).

Department of Health and Human Services, Office of Inspector General. *Review of Pharmacy Acquisition Costs for Drugs Reimbursed Under the Medicaid Prescription Drug Program of the Missouri Department of Social Services.* January 1997. (A-06-95-00067).

Department of Health and Human Services, Office of Inspector General. *Review of Pharmacy Acquisition Costs for Drugs Reimbursed Under the Medicaid Prescription Drug Program of the Montana Department of Health and Human Services.* July 1996. (A-06-95-00068).

Department of Health and Human Services, Office of Inspector General. *Review of Pharmacy Acquisition Costs for Drugs Reimbursed Under the Medicaid Prescription Drug Program of the Montana Department of Health and Human Services*. February 2002. (A-06-01-00005).

Department of Health and Human Services, Office of Inspector General. *Review of Pharmacy Acquisition Costs for Drugs Reimbursed Under the Medicaid Prescription Drug Program of the Texas Health and Human Services Commission*. November 2001. (A-06-01-00001).

Department of Health and Human Services, Office of Inspector General. *Review of Pharmacy Acquisition Costs for Drugs Reimbursed Under the Medicaid Prescription Drug Program of the Virginia Department of Medical Assistance Services*. November 1996. (A-06-95-00072).

Department of Health and Human Services, Office of Inspector General. *Review of Pharmacy Acquisition Costs for Drugs Reimbursed Under the Medicaid Prescription Drug Program of the West Virginia Department of Health and Human Resources*. December 2001. (A-06-01-00007).

Department of Health and Human Services, Office of Inspector General. *Semiannual Report, April 1, 1997 – September 30, 1997*.

Department of Health and Human Services, Office of Inspector General. *Suppliers' Acquisition Costs for Albuterol Sulfate*. June 1996. (OEI-03-94-00393).

Department of Health and Human Services, Office of Inspector General. *Update: Excessive Medicare Reimbursement For Albuterol*. January 2004. (OEI-03-03-00510).

Department of Health and Human Services, Office of Inspector General. *Use of Average Wholesale Prices in Reimbursing Pharmacies Participating in Medicaid and the Medicare Prescription Drug Program*. October 1989. (A-06-89-00037).

Department of Health and Human Services, Office of Audit. *Changes to the Medicaid Prescription Drug Program Could Save Millions*. 1984.

Department of Health, Education, and Welfare, Office of the Secretary. *U.S. Task Force on Prescription Drugs: The Drug Makers and The Drug Distributors*. December 1968.

Federal Register. November 15, 1974. Vol. 39, No. 222, 45 CFR Part 19. p. 40303.

Federal Register. July 31, 1975. Vol. 40, No. 148, 45 CFR Part 19. p. 32293.

Federal Register. August 20, 2003. Vol. 68, No. 161, 42 CFR Part 405. pp. 50428-50452.

Federal Register. January 7, 2004. Vol. 69, No. 4, 42 CFR Parts 405 and 414. pp. 1084-1132.

Gencarelli, Dawn M. "Average Wholesale Price for Prescription Drugs: Is There a More Appropriate Pricing Mechanism," *National Health Policy Forum Issue Brief No. 775*. George Washington University, June 7, 2002.

General Accounting Office. *Medicaid Changes in Drug Prices Paid by HMOs and Hospitals Since Enactment of Rebate Provisions*. January 1993. (GAO/HRD-93-43)

General Accounting Office. *Medicare: Payments for Covered Outpatient Drugs Exceed Providers' Cost* (Report to Congressional Committees). September 2001. (GAO-01-1118).

General Accounting Office. *Prescription Drugs: Changes in Prices for Selected Drugs* (Report to Congressional Requesters). August 1992. (GAO/HRD-92-128).

Government Accountability Office. *Medicaid Outpatient Prescription Drugs: Estimated 2007 Federal Upper Limits for Reimbursement Compared with Retail Pharmacy Acquisition Costs*. December 22, 2006. (GAO-07-239R).

Government Accountability Office. *Medicare Chemotherapy Payments: New Drug and Administration Fees Are Closer to Providers' Costs*. December 1, 2004. (GAO-05-142R).

Government Accountability Office. *Prescription Drugs: An Overview of Approaches to Negotiate Drug Prices Used by Other Countries and U.S. Private Payers and Federal Programs*. January 11, 2007. (GAO-07-358T).

Gray, Tom. "Construction Ahead." *Homecare*, October 1, 2002.  
[http://homecaremag.com/mag/medical\\_construction\\_ahead/](http://homecaremag.com/mag/medical_construction_ahead/).

Gumbhir, Ashok and Johnny Anderson. *Reimbursement for Pharmaceutical Services in Missouri*. Final Report submitted to Missouri Department of Social Services, Division of Medical Care, March 1991.

MASSPIRG. "Consumer Groups Charge Industry-Wide Price Manipulation - Over \$800 Million in Illegal Profits from Medicare & Medicare Patients." <http://masspirg.org/MA.asp?id2=5310&id3=MA&>.

Letter from Nancy-Ann Min DeParle, Department of Health and Human Services, Health Care Financing Administration, to Members of Congress. September 8, 2000.

Pear, Robert. "Administration Plans Cuts in Some Drug Payments." *The New York Times*, August 6, 2000.

Medicare Payment Advisory Commission (MedPAC). *Report to the Congress: Variation and Innovation in Medicare*. June 2003.

Rozek, Richard P. and Ruth Berkowitz. "The Costs to the U.S. Health Care System of Extending Marketing Exclusivity for Taxol." *Journal of Research in Pharmaceutical Economics*, Vol. 9(4) (1999): pp. 21-41.

Schondelmeyer, Stephen W. and Marian V. Wrobel. *Medicaid and Medicare Drug Pricing: Strategy to Determine Market Prices*. Final Report submitted by Abt Associates Inc. to the Centers for Medicare and Medicaid Services, August 30, 2004.

Spears, James M. and Jeff Pearlman. "Using Litigation to Regulate Drug Prices: The Assault on 'AWP'." Washington Legal Foundation, Critical Legal Issues, Working Paper Series No. 107. February 2002.

State of Utah, Department of Health, Division of Health Care Financing. *Medicaid Pharmacy—Acquisition Cost of Generic Prescription Drug Products*. February 1999.

U.S. Congress. House. Committee on Energy and Commerce. *Hearing: Medicaid and AWP Hearing: Medicaid Prescription Drug Reimbursement: Why the Government Pays Too Much.* December 7, 2004. <http://globalag.igc.org/health/us/2004/toomuch.pdf>.

U.S. Congress. House. Committee on Energy and Commerce, Subcommittee on Oversight and Investigations. *Testimony of George Reeb, Assistant Inspector General, Centers for Medicare and Medicaid Audits, Office of Inspector General, U.S. Department of Health and Human Services.* December 7, 2004.

U.S. Congress. House. Committee on Ways and Means, Subcommittee on Health. *Testimony of George Reeb, Assistant Inspector General, Centers for Medicare and Medicaid Audits, Department of Health and Human Services.* October 3, 2002.

U.S. Congress. Senate. Special Committee on Aging. *CBO Testimony of Douglas Holtz-Eakin (Payments for Prescription Drugs Under Medicaid).* July 20, 2005.

### **Miscellaneous**

42 CFR § 447.332.

American Medical Association. "AMA Downloadable Resource Table: Asthma." ASTHMA Version 3.0 July 2007. [www.ama-assn.org/ama1/pub/upload/mm/370/astcodingspecs307\\_7.xls](http://www.ama-assn.org/ama1/pub/upload/mm/370/astcodingspecs307_7.xls).

Centers for Medicare and Medicaid Services. "[Sample] REBATE AGREEMENT Between The Secretary of Health and Human Services (hereinafter referred to as 'the Secretary') and The Manufacturer Identified in Section XI of this Agreement (hereinafter referred to as 'the Labeler')."  
<http://www.cms.hhs.gov/MedicaidDrugRebateProgram/downloads/rebateagreement.pdf>.

Congressional Research Service (CRS). "P.L. 110-275: The Medicare Improvements for Patients and Providers Act of 2008" (CRS Report for Congress). July 23, 2008.  
<http://www.ohanet.org/finance/medicare/HR6331CMSSummary.pdf>.

Department of Health and Human Services, Health Care Financing Administration. "Federal Upper Limit (FUL) Changes to Transmittal No. 37." Current as of August 20, 2008.

Department of Health and Human Services, Health Care Financing Administration. "Federal Upper Limit Drug Changes to Transmittal No. 36 Dated April 2000 - Effective December 7, 2000".

Department of Health and Human Services, Health Care Financing Administration. "State Medicaid Manual: Part 6 - Payment for Services." Transmittal Nos. 45-6 Thru Rev. 13 (Reprint Date August 1989), 14 (August 1989), 15 (September 1989), 16 (March 1990), 17 (April 1990), 18 (July 1990), 19 (August 1991), 20 (March 1992), 21 (October 1992), 22 (April 1993), 23 (August 1993), 24 (October 1993), 25 (May 1994), 26 (October 1994), 27 (January 1995), 28 (May 1995), 29 (October 1995), 30 (June 1996), 31 (July 1996), 32 (November 1996), 33 (March 1997), 34 (July 1997), 35 (July 1998), 36 (April 2000), 36 (November 2000), and 37 (November 2001).

FloridaInfusion, Nations Drug Pharmaceutical Distributor. Product Search, Accessed February 6, 2009.  
<http://www.floridainfusion.com/awps.asp?keyword=capoten&searchfield=keyword>.

National Association of Chain Drug Stores. "Judge Grants AMP Rule Injunction."  
<http://www.nacds.org/wmspage.cfm?parm1=5557>.

National Association of Chain Drug Stores & National Community Pharmacists Association. "Frequently Asked Questions (FAQs) Lawsuit Filed by NACDS and NCPA Against CMS Challenging AMP Rule November 7, 2007." November 6, 2007. [http://www.ncpanet.org/pdf/amp\\_ncpanacds-lawsuitfaq.pdf](http://www.ncpanet.org/pdf/amp_ncpanacds-lawsuitfaq.pdf).

Rhode Island Medical Assistance Program, Provider Update Newsletter, Vol. 74. December 1998.  
<http://www.dhs.state.ri.us/dhs/heacre/prosvcs/prvupdts/pu74.htm>.

U.S. Food and Drug Administration, Center for Drug Evaluation and Research. *Approved Drug Products with Therapeutic Equivalence Evaluations*. 11<sup>th</sup> Edition (1991) through 27<sup>th</sup> Edition (2007).

U.S. Food and Drug Administration, Center for Drug Evaluation and Research. "National Drug Code Directory." Current through December 3, 2008. <http://www.fda.gov/cder/ndc/database>.

**Exhibit 3**

**FULs for which a Lower FUL, with at Least Three Lower WACs, Could Have Been Selected at the Time the FUL was Set<sup>1</sup>**  
**Using Published Compendia WACs<sup>2</sup> for Therapeutically Equivalent NDCs of the Package Size Used to Set the FUL<sup>3</sup>**  
**Federal Upper Limits: 1997 - 2005**

GCN	Description <sup>4</sup>	Current Month <sup>5</sup>	Start Date	End Date <sup>6</sup>	Actual FUL	Alternative FUL <sup>7</sup> (Dollars)	Lower WACs <sup>8</sup>
(a)	(b)	(c)	(d)	(e)	(f)	(g)	(h)
005037	Albuterol 0.09 mg/inh, aerosol, metered, inhalation, 17 gm	Jan 2000	12/07/00	12/07/00	\$ 0.3490	\$ 0.3309	\$ 0.2835 0.2794 0.2412 0.2206
005039	Albuterol Sulfate Eq 0.083% base, Solution, Inhalation, 3 ml	Apr 2001	01/22/02	05/07/05	0.1450	0.1150	0.1067 0.0967 0.0933 0.0900 0.0891 0.0886 0.0800 0.0800 0.0769 0.0767
005039	Albuterol Sulfate Eq 0.083% Base, Solution, Inhalation, 3 ml			05/08/05	0.1150	0.0627	0.0573 0.0507 0.0507 0.0507 0.0419 0.0418
048262	Cefadroxil Eq 500 mg base, Capsule, Oral, 50	Apr 2001	01/22/02	03/10/03	3.0789	2.9325 <sup>9</sup>	2.4400 2.1233 2.1233 1.9550 0.8499
004560	Clonazepam 0.5 mg, Tablet, Oral 100	Jun 1997	10/01/97	08/31/98	0.8702	0.8190	0.6999 0.6683 0.5661 0.5460 0.5460
004560	Clonazepam 0.5 mg, Tablet, Oral, 100	Jan 2000	12/07/00	01/21/02	0.2760	0.2003	0.1840 0.1774 0.1738 0.1635 0.1335 0.0931
004560	Clonazepam 0.5 mg, Tablet, Oral, 100	Apr 2001	01/22/02		0.2455	0.2453	0.2018 0.1841 0.1840 0.1774 0.1738 0.1738 0.1700

**Exhibit 3**

**FULs for which a Lower FUL, with at Least Three Lower WACs, Could Have Been Selected at the Time the FUL was Set<sup>1</sup>**  
**Using Published Compendia WACs<sup>2</sup> for Therapeutically Equivalent NDCs of the Package Size Used to Set the FUL<sup>3</sup>**  
**Federal Upper Limits: 1997 - 2005**

GCN	Description <sup>4</sup>	Current Month <sup>5</sup>	Start Date	End Date <sup>6</sup>	Actual FUL	Alternative FUL <sup>7</sup> (Dollars)	Lower WACs <sup>8</sup>
(a)	(b)	(c)	(d)	(e)	(f)	(g)	(h)
							0.1637
							0.1635
							0.0931
							0.0799
000386	Enalapril Maleate 20 mg, Tablet, Oral, 100		08/24/03		0.9150	0.2475	0.1700
							0.1650
							0.1650
003758	Lorazepam 1 mg, Tablet, Oral 100	Jan 1994	07/01/94	09/30/97	0.0207	0.0182	0.0173
							0.0165
							0.0152
							0.0149
							0.0138
							0.0135
							0.0122
							0.0121
003758	Lorazepam 1 mg, Tablet, Oral 100	Jun 1997	10/01/97	02/11/98	0.0203	0.0182	0.0180
							0.0175
							0.0174
							0.0173
							0.0170
							0.0165
							0.0161
							0.0156
							0.0152
							0.0140
							0.0135
							0.0134
							0.0121
003758	Lorazepam 1 mg, Tablet, Oral 100	Apr 1998	09/01/98	12/06/00	0.6684	0.0182	0.0175
							0.0161
							0.0156
							0.0152
							0.0135
							0.0121
003758	Lorazepam 1 mg, Tablet, Oral, 100	Jan 2000	12/07/00		0.5718	0.3299	0.2199
							0.0135
							0.0121
005131	Metoprolol 100 mg, Tablet, Oral 100	Oct 1996	01/01/97	09/30/97	0.1185	0.1161	0.1150
							0.1150
							0.1140
							0.1100
							0.1088
							0.1022
							0.0988

**Exhibit 3**

**FULs for which a Lower FUL, with at Least Three Lower WACs, Could Have Been Selected at the Time the FUL was Set<sup>1</sup>  
Using Published Compendia WACs<sup>2</sup> for Therapeutically Equivalent NDCs of the Package Size Used to Set the FUL<sup>3</sup>  
Federal Upper Limits: 1997 - 2005**

GCN	Description <sup>4</sup>	Current Month <sup>5</sup>	Start Date	End Date <sup>6</sup>	Actual FUL	Alternative FUL <sup>7</sup> (Dollars)	Lower WACs <sup>8</sup>
(a)	(b)	(c)	(d)	(e)	(f)	(g)	(h)
							0.0971
							0.0971
							0.0886
							0.0860
							0.0774
005131	Metoprolol 100 mg, Tablet, Oral 100	Jun 1997	10/01/97	08/31/98	0.1161	0.0878	0.0860
							0.0800
							0.0800
							0.0783
							0.0783
							0.0750
							0.0609
							0.0585
005131	Metoprolol 100 mg, Tablet, Oral 100	Apr 1998	09/01/98	12/06/00	0.0878	0.0675	0.0609
							0.0609
							0.0609
							0.0450
005131	Metoprolol 100 mg, Tablet, Oral, 100	Jan 2000	12/07/00	01/21/02	0.1290	0.0854	0.0725
							0.0609
							0.0609
							0.0609
							0.0569
005131	Metoprolol 100 mg, Tablet, Oral, 100	Apr 2001	01/22/02	10/27/04	0.0914	0.0690	0.0618
							0.0609
							0.0609
							0.0569
							0.0544
							0.0544
							0.0460
011673	Ranitidine Eq 150 mg Base, Tablet, Oral, 100		09/24/98	09/21/99	0.5914 <sup>10</sup>	0.4950	0.4880
							0.3685
							0.3450
							0.3300
							0.2135
011673	Ranitidine Eq 150 mg Base, Tablet, Oral, 100	Jan 2000	12/07/00	01/21/02	0.3410	0.2633	0.2548
							0.2275
							0.2135
							0.1755
							0.0521
011673	Ranitidine Eq 150 mg Base, Tablet, Oral, 100	Apr 2001	01/22/02	05/07/05	0.3411	0.2633	0.2275
							0.2275
							0.2275

**Exhibit 3**

**FULs for which a Lower FUL, with at Least Three Lower WACs, Could Have Been Selected at the Time the FUL was Set<sup>1</sup>**  
**Using Published Compendia WACs<sup>2</sup> for Therapeutically Equivalent NDCs of the Package Size Used to Set the FUL<sup>3</sup>**  
**Federal Upper Limits: 1997 - 2005**

GCN	Description <sup>4</sup>	Current Month <sup>5</sup>	Start Date	End Date <sup>6</sup>	Actual FUL	Alternative FUL <sup>7</sup>	Lower WACs <sup>8</sup>
(a)	(b)	(c)	(d)	(e)	(f)	(g)	(h)
							0.2275
							0.2135
							0.1755
							0.0725

- Notes:
- Analysis of each GCN includes: (1) products explicitly identified by the First DataBank (FDB) variable "GCN Sequence Number" as belonging to the GCN; (2) any similarly described products (based on name, strength, and dosage form) not listed in FDB that appear in Medispan or Red Book and not exclusively in another GCN in FDB at the NDC-9 level. Finally, following a review of online sources for NDCs that do not appear in FDB at the NDC-11 or NDC-9 level (355 NDCs in total), seven NDCs were dropped from the analysis (52493084701, 52493084717, 54977069501, 54977070601, 57362011601, 63874074917, and 51655027924), as either they were described as albuterol inhaler refills and not as albuterol inhalers or discrepancies in their descriptions were resolved such that they were confirmed to be outside the GCN.
  - Some NDCs are reported under different GCNs in the FDB annual product description files at the NDC-11 level (15 NDCs) and, if the NDC does not appear in FDB at the 11-digit level, at the NDC-9 level (9 NDCs). In addition, some NDCs appear under different Package IDs in Red Book (6 NDCs). These differences, generally, are time dependent. With respect to FDB, any descriptive values (e.g., therapeutic equivalency rating or obsolete date) reported for an NDC while it is listed under a GCN other than those at issue are excluded from the analysis, as are any price postings that correspond to the time period when the NDC appears to correspond to another product and was listed under a different GCN. With respect to Red Book, the Package ID represents a unique identifier by which an NDC's product description, package size, therapeutic equivalence rating, deactivation/reactivation dates, and prices are reported. Package IDs, and all associated data, that correspond to a drug name other than those at issue are excluded.
  - For all compendia, postings of zero invalidate the previously posted price. For Red Book, postings are treated as active through the price deactivation date or until the next posting. Deactivation dates that fall before the date of the posting are replaced with the date of the posting (2 instances in total for WAC postings). Finally, deactivation dates that occur on or after the date of a subsequent posting are replaced with the date immediately preceding the date of the next posting (3 instances in total for WAC postings).
  - No postings are available from Medispan after August 3, 2007 and from FDB after February 1, 2007. Although postings are available in Red Book as late as April 2009, they are not used after June 9, 2008, the date the data were acquired. FULs analyzed are those for which any portion of their effective life falls within the period 1997 to 2005; however, the analysis extends over the full effective life of these FULs.

<sup>1</sup> For each of the above FULs, a lower FUL, with at least three lower WACs, could have been selected at the time the FUL was set. The lower WACs, which include the basis for the alternative FUL, do not include duplicate postings, such as two WACs for the same NDC for which the difference between the two prices is equal to zero when rounded to four decimals. Nor does this count include duplicate postings for the same product, as occurs when the NDC for a product changes. Also see Note 2 for additional qualifications concerning the time period of the WACs.

<sup>2</sup> WACs are based on published compendia WACs reported by Medispan, FDB, and Red Book. Each WAC must be active (i.e., the price has not been deactivated by obsolescence, a subsequent price posting, or otherwise) for the entire month specified in the CMS transmittal as the month during which prices analyzed to set the FUL were current (see Note 5). Obsolescence, generally, is determined with reference to the FDB "Obsolete Date", the FDB "HCFA Termination Date", the Medispan "Inactive Date", and the Red Book "NDC Discontinuation Date" (collectively, the "end dates"). WACs are only analyzed during the period prior to the earliest of the four end dates. However, any postings on or after the earliest end date are treated as a reactivation of the NDC and such postings are analyzed until the next end date. Postings after the second, third, or fourth end date are treated in the same manner. Similarly, the Red Book "Reactivation Date" can reactivate the most recent set of active prices for an NDC, assuming the date falls on or after the discontinuation date and the NDC is not already currently active. Finally, 33 NDCs among the nine GCNs, for which the FDB Obsolete Date exhibited stark inconsistencies across annual files, were examined separately, using price posting activity and CMS reimbursement.

<sup>3</sup> An NDC is considered therapeutically equivalent if it was found to have an "A" rating in the available copies of the FDA's *Approved Drug Products with Therapeutic Equivalence Evaluations* (i.e., the Orange Book) or, if such information was not available, was "A" rated by either the FDB variable "Expanded Orange Book Code" or the Red Book variable "Orange Book Code". Since the ratings in the Orange Book are reported by drug application number, the FDA's National Drug Code Directory was used to link each application number to an NDC. An NDC is considered to be of the same package size as that used to set the FUL if the package size indicated in the CMS transmittal matches either the FDB variable "Package Size", the Red Book variables "Total Quantity - Actual" or "Standard Quantity - Actual", or the Medispan implied package size (the mean ratio between the package and unit prices, rounded to one decimal). Data from each of the three pricing compendia are considered publicly available as of the date of the first AWP, WAC, or Direct Price posting reported by each compendium for the relevant NDC. For FDB descriptive data, contemporaneous data are used from the appropriate annual file and any changes across these files are recognized as of the beginning of the year of the file in which the change appears. Changes across editions of the Orange Book are recognized as of the publication date of the edition in which the change appears, or April 30th (based on a survey of the different publication dates that were observable (1991 -

**Exhibit 3**

**FULs for which a Lower FUL, with at Least Three Lower WACs, Could Have Been Selected at the Time the FUL was Set<sup>1</sup>**  
**Using Published Compendia WACs<sup>2</sup> for Therapeutically Equivalent NDCs of the Package Size Used to Set the FUL<sup>3</sup>**  
**Federal Upper Limits: 1997 - 2005**

GCN	Description <sup>4</sup>	Current Month <sup>5</sup>	Start Date	End Date <sup>6</sup>	Actual FUL	Alternative FUL <sup>7</sup>	Lower WACs <sup>8</sup>
(a)	(b)	(c)	(d)	(e)	(f)	(g)	(h)

05/23/91; 1993 - 04/22/93; 1994 - 06/16/94; 1996 - 05/29/96; 2001 - 04/02/01; 2002 - 04/16/02; 2003 - 03/18/03; 2007 - 05/21/07)) if the publication date was unavailable. The package size and therapeutical equivalence requirements must both be met as of the beginning of the FUL current month.

<sup>4</sup> Product descriptions are taken from the CMS transmittal in which the FUL is reported. The package size used to set the FUL for each GCN is indicated by the value at the end of each description and remains constant for all 9 GCNs except for cefadroxil, which changed from 100 to 50 as of the January 22, 2002 FUL.

<sup>5</sup> CMS transmittals typically indicate the month as of which prices analyzed to set the FUL were current, i.e., the "current month". Where the current month was not available, the period considered was the three-month period preceding the relevant FUL's effective date.

<sup>6</sup> Missing end dates indicate FULs that were still in effect as of June 9, 2008, according to Red Book and CMS transmittals.

<sup>7</sup> The "Alternative FUL" is based on the lowest WAC for which the implied FUL is greater than at least 3 WACs. The implied FUL is calculated by multiplying the WAC by 1.5 and rounding to four decimals.

<sup>8</sup> WACs are displayed rounded to four decimals.

<sup>9</sup> Although the specified FUL was set on the basis of a package size of 50, by far the most commonly used package size is 100. Hence the alternative FUL is based on a package size of 100.

<sup>10</sup> This is the only FUL in the table that does not appear in one of the CMS transmittals cited below. However, the FUL is published by both Medispan and FDB. In addition, a provider update, published by the Rhode Island Medical Assistance Program in December 1998, notified pharmacy providers that, effective immediately, "Ranitidine HCL, 150mg, tablet, \$0.5914/each" had been added to the FUL list. The product description in the table is based on the description listed in the CMS transmittals for the subsequent FUL.

- Sources:
- American Medical Association, *AMA Downloadable Resource Table: Asthma*, ASTHMA Version 3.0 July 2007, <[www.ama-assn.org/ama1/pub/upload/mm/370/astcodingspecs307\\_7.xls](http://www.ama-assn.org/ama1/pub/upload/mm/370/astcodingspecs307_7.xls)>.
  - "Comprehensive Price History File," 2007 Wolters Kluwer Health (Medispan).
  - Department of Health and Human Services, Health Care Financing Administration, "Federal Upper Limit (FUL) Changes to Transmittal No. 37," Current as of August 20, 2008.
  - Department of Health and Human Services, Health Care Financing Administration, "Federal Upper Limit Drug Changes to Transmittal No. 36 Dated April 2000 - Effective December 7, 2000".
  - Department of Health and Human Services, Health Care Financing Administration, "State Medicaid Manual: Part 6 - Payment for Services," Transmittal Nos. 45-6 Thru Rev. 13 (Reprint Date August 1989), 14 (August 1989), 15 (September 1989), 16 (March 1990), 17 (April 1990), 18 (July 1990), 19 (August 1991), 20 (March 1992), 21 (October 1992), 22 (April 1993), 23 (August 1993), 24 (October 1993), 25 (May 1994), 26 (October 1994), 27 (January 1995), 28 (May 1995), 29 (October 1995), 30 (June 1996), 31 (July 1996), 32 (November 1996), 33 (March 1997), 34 (July 1997), 35 (July 1998), 36 (April 2000), 36 (November 2000), and 37 (November 2001).
  - First DataBank (Alabama Production) Data and NDDF (*National Drug Data File*) Documentation Manual (Rev. April 2000).
  - FloridaInfusion, Nations Drug, Accessed February 6, 2009 <<http://www.floridainfusion.com/awps.asp?keyword=capoten&searchfield=keyword>>.
  - Medicaid State Drug Utilization Data including "Definitions for State Drug Utilization Data Specifications", Centers for Medicare & Medicaid Services.
  - Medispan Inactive Dates, 2007 Wolters Kluwer Health (Medispan).
  - Red Book Advanced Data and *Red Book™ Drug Products and Pricing Developer's Guide Advanced* (January 2008).
  - Rhode Island Medical Assistance Program, Provider Update Newsletter, Vol. 74, December 1998, <<http://www.dhs.state.ri.us/dhs/heacre/provservs/prvupdts/pu74.htm>>.
  - U.S. Food and Drug Administration, Center for Drug Evaluation and Research, *Approved Drug Products with Therapeutic Equivalence Evaluations*, 11th Edition - 27th Edition.
  - U.S. Food and Drug Administration, Center for Drug Evaluation and Research, *National Drug Code Directory*, <<http://www.fda.gov/cder/ndc/database/>>.

**Exhibit 4**

**FULs for which at Least Three Lower WACs Could Not Be Identified at the Time the FUL was Set<sup>1</sup>  
Using Published Compendia WACs<sup>2</sup> for Therapeutically Equivalent NDCs of the Package Size Used to Set the FUL<sup>3</sup>  
Federal Upper Limits: 1997 - 2005**

GCN	Description <sup>4</sup>	Current Month <sup>5</sup>	Start Date	End Date <sup>6</sup>	FUL	Lower WACs	
						WACs <sup>7</sup>	Active for Entire Period <sup>8</sup>
(a)	(b)	(c)	(d)	(e)	(f)	(g)	(h)
005037	Albuterol 0.09 mg, Aerosol, Metered, Inhalation, 17 gm		05/08/05	04/09/06	\$ 0.3088	\$ 0.2912 0.2059	N Y
004560	Clonazepam 0.5 mg, Tablet, Oral 100	Apr 1998	09/01/98	12/06/00	0.4146 <sup>9</sup>	0.4044 <sup>10</sup> 0.2369	N N
017297	Isosorbide MN 60 mg, Tablet, Extended Release, Oral, 100	Apr 2001	01/22/02	07/20/05	0.7492	0.5625 0.4995	Y Y
017297	Isosorbide MN 60 mg, Tablet, Extended Release, Oral, 100			07/21/05		0.2025	0.0525
							Y

- Notes:
- Analysis of each GCN includes: (1) products explicitly identified by the First DataBank (FDB) variable "GCN Sequence Number" as belonging to the GCN; (2) any similarly described products (based on name, strength, and dosage form) not listed in FDB that appear in Medispan or Red Book and not exclusively in another GCN in FDB at the NDC-9 level. Finally, following a review of online sources for NDCs that do not appear in FDB at the NDC-11 or NDC-9 level (355 NDCs in total), seven NDCs were dropped from the analysis (52493084701, 52493084717, 54977069501, 54977070601, 57362011601, 63874074917, and 51655027924), as either they were described as albuterol inhaler refills and not as albuterol inhalers or discrepancies in their descriptions were resolved such that they were confirmed to be outside the GCN.
  - Some NDCs are reported under different GCNs in the FDB annual product description files at the NDC-11 level (15 NDCs) and, if the NDC does not appear in FDB at the 11-digit level, at the NDC-9 level (9 NDCs). In addition, some NDCs appear under different Package IDs in Red Book (6 NDCs). These differences, generally, are time dependent. With respect to FDB, any descriptive values (e.g., therapeutic equivalency rating or obsolete date) reported for an NDC while it is listed under a GCN other than those at issue are excluded from the analysis, as are any price postings that correspond to the time period when the NDC appears to correspond to another product and was listed under a different GCN. With respect to Red Book, the Package ID represents a unique identifier by which an NDC's product description, package size, therapeutic equivalence rating, deactivation/reactivation dates, and prices are reported. Package IDs, and all associated data, that correspond to a drug name other than those at issue are excluded.
  - For all compendia, postings of zero invalidate the previously posted price. For Red Book, postings are treated as active through the price deactivation date or until the next posting. Deactivation dates that fall before the date of the posting are replaced with the date of the posting (3 instances in total for WAC and Direct Price postings). Finally, deactivation dates that occur on or after the date of a subsequent posting are replaced with the date immediately preceding the date of the next posting (3 instances in total for WAC and Direct Price postings).
  - No postings are available from Medispan after August 3, 2007 and from FDB after February 1, 2007. Although postings are available in Red Book as late as April 2009, they are not used after June 9, 2008, the date the data were acquired. FULs analyzed are those for which any portion of their effective life falls within the period 1997 to 2005; however, the analysis extends over the full effective life of these FULs.

<sup>1</sup> There were less than three lower WACs, for each of the above FULs, simultaneously available at any given point in time during the month specified in the CMS transmittal as the month during which prices analyzed to set the FUL were current, i.e., the "current month" (also see Note 5). Duplicate postings for the same NDC, such as two WACs for which the difference between the two prices is equal to zero when rounded to four decimals, are only counted once. Similarly, duplicate postings for the same product, as occurs when the NDC for a product changes and a duplicate posting is reported for each NDC, are also only counted once.

<sup>2</sup> WACs are based on published compendia prices reported by Medispan, FDB, and Red Book. Each WAC must be active (i.e., the price has not been deactivated by obsolescence, a subsequent price posting, or otherwise) for at least part of the current month. Obsolescence, generally, is determined with reference to the FDB "Obsolete Date", the FDB "HCFA Termination Date", the Medispan "Inactive Date", and the Red Book "NDC Discontinuation Date" (collectively, the "end dates"). WACs are only analyzed during the period prior to the earliest of the four end dates. However, any postings on or after the earliest end date are treated as a reactivation of the NDC and such postings are analyzed until the next end date. Postings after the second, third, or fourth end date are treated in the same manner. Similarly, the Red Book "Reactivation Date" can reactivate the most recent set of active prices for an NDC, assuming the date falls on or after the discontinuation date and the NDC is not already currently active. Finally, 33 NDCs among the nine GCNs, for which the FDB Obsolete Date exhibited stark inconsistencies across annual files, were examined separately, using price posting activity and CMS reimbursement.

**Exhibit 4**

**FULs for which at Least Three Lower WACs Could Not Be Identified at the Time the FUL was Set<sup>1</sup>  
Using Published Compendia WACs<sup>2</sup> for Therapeutically Equivalent NDCs of the Package Size Used to Set the FUL<sup>3</sup>  
Federal Upper Limits: 1997 - 2005**

<sup>3</sup> An NDC is considered therapeutically equivalent if it was found to have an "A" rating in the available copies of the FDA's *Approved Drug Products with Therapeutic Equivalence Evaluations* (i.e., the Orange Book) or, if such information was not available, was "A" rated by either the FDB variable "Expanded Orange Book Code" or the Red Book variable "Orange Book Code". Since the ratings in the Orange Book are reported by drug application number, the FDA's National Drug Code Directory was used to link each application number to an NDC. An NDC is considered to be of the same package size as that used to set the FUL if the package size indicated in the CMS transmittal matches either the FDB variable "Package Size", the Red Book variables "Total Quantity - Actual" or "Standard Quantity - Actual", or the Medispan implied package size (the mean ratio between the package and unit prices, rounded to one decimal). Data from each of the three pricing compendia are considered publicly available as of the date of the first AWP, WAC, or Direct Price posting reported by each compendium for the relevant NDC. For FDB descriptive data, contemporaneous data are used from the appropriate annual file and any changes across these files are recognized as of the beginning of the year of the file in which the change appears. Changes across editions of the Orange Book are recognized as of the publication date of the edition in which the change appears, or April 30th (based on a survey of the different publication dates that were observable (1991 - 05/23/91; 1993 - 04/22/93; 1994 - 06/16/94; 1996 - 05/29/96; 2001 - 04/02/01; 2002 - 04/16/02; 2003 - 03/18/03; 2007 - 05/21/07)) if the publication date was unavailable. The package size and therapeutic equivalence requirements must both be met as of the beginning of the FUL current month.

<sup>4</sup> Product descriptions are taken from the CMS transmittal in which the FUL is reported. The package size used to set the FUL for each GCN is indicated by the value at the end of each description and remains constant for all 9 GCNs except for cefadroxil, which changed from 100 to 50 as of the January 22, 2002 FUL.

<sup>5</sup> CMS transmittals typically indicate the month as of which prices analyzed to set the FUL were current, i.e., the "current month". Where the current month was not available, the period considered was the three-month period preceding the relevant FUL's effective date.

<sup>6</sup> Missing end dates indicate FULs that were still in effect as of June 9, 2008, according to Red Book and CMS transmittals.

<sup>7</sup> WACs are displayed rounded to four decimals.

<sup>8</sup> "Active for Entire Period" indicates whether the listed WAC(s) were active for the entire current month, or for the entire three month period preceding the FUL effective date if the current month was not specified in the CMS transmittal.

<sup>9</sup> If Direct Prices can be used interchangeably with WACs, when searching for three lower WACs, a third lower price can be found for this FUL. In particular, a Direct Price of \$0.25170 is reported for NDC 00093083201 on April 30, 1998. This is the same NDC for which the listed WAC of \$0.2369 is reported.

<sup>10</sup> The listed WAC was replaced with a WAC of \$0.26320 on April 8, 1998. Hence although the listed WAC was only in effect for part of the current month, the underlying NDC had a WAC lower than the FUL for the entire current month.

- Sources:
- American Medical Association, *AMA Downloadable Resource Table: Asthma*, ASTHMA Version 3.0 July 2007, <[www.ama-assn.org/ama1/pub/upload/mm/370/astcodingspecs307\\_7.xls](http://www.ama-assn.org/ama1/pub/upload/mm/370/astcodingspecs307_7.xls)>.
  - "Comprehensive Price History File," 2007 Wolters Kluwer Health (Medispan).
  - Department of Health and Human Services, Health Care Financing Administration, "Federal Upper Limit (FUL) Changes to Transmittal No. 37," Current as of August 20, 2008.
  - Department of Health and Human Services, Health Care Financing Administration, "Federal Upper Limit Drug Changes to Transmittal No. 36 Dated April 2000 - Effective December 7, 2000".
  - Department of Health and Human Services, Health Care Financing Administration, "State Medicaid Manual: Part 6 - Payment for Services," Transmittal Nos. 45-6 Thru Rev. 13 (Reprint Date August 1989), 14 (August 1989), 15 (September 1989), 16 (March 1990), 17 (April 1990), 18 (July 1990), 19 (August 1991), 20 (March 1992), 21 (October 1992), 22 (April 1993), 23 (August 1993), 24 (October 1993), 25 (May 1994), 26 (October 1994), 27 (January 1995), 28 (May 1995), 29 (October 1995), 30 (June 1996), 31 (July 1996), 32 (November 1996), 33 (March 1997), 34 (July 1997), 35 (July 1998), 36 (April 2000), 36 (November 2000), and 37 (November 2001).
  - First DataBank (Alabama Production) Data and *NDDF (National Drug Data File)™ Documentation Manual* (Rev. April 2000).
  - FloridaInfusion, Nations Drug, Accessed February 6, 2009 <<http://www.floridainfusion.com/awps.asp?keyword=capoten&searchfield=keyword>>.
  - Medicaid State Drug Utilization Data including "Definitions for State Drug Utilization Data Specifications", Centers for Medicare & Medicaid Services.
  - Medispan Inactive Dates, 2007 Wolters Kluwer Health (Medispan).
  - Red Book Advanced Data and *Red Book™ Drug Products and Pricing Developer's Guide Advanced* (January 2008).
  - Rhode Island Medical Assistance Program, Provider Update Newsletter, Vol. 74, December 1998, <<http://www.dhs.state.ri.us/dhs/heacre/provservs/prvupdts/pu74.htm>>.
  - U.S. Food and Drug Administration, Center for Drug Evaluation and Research, *Approved Drug Products with Therapeutic Equivalence Evaluations*, 11th Edition - 27th Edition.
  - U.S. Food and Drug Administration, Center for Drug Evaluation and Research, *National Drug Code Directory*, <<http://www.fda.gov/cder/ndc/database/>>.

**Exhibit 5**  
**Summary of Nonconformities with Ms. Gaston's Rule**  
**Federal Upper Limits: 1997 - 2005**

GCN	Description	FDB FUL	Current Month	Start Date	End Date	Nonconformity with Gaston Declaration <sup>1</sup>
(a)	(b)	(c)	(d)	(e)	(f)	(g)
005037	Albuterol 0.09 mg/inh, Aerosol, Metered, Inhalation, 17 gm	\$ 0.4394 0.3490 0.8823 0.3088	Jun 1997 Jan 2000 03/11/03 05/08/05	10/01/97 12/07/00 05/07/05 04/09/06	12/06/00 12/07/00 05/07/05 04/09/06	None Too High None Too Low
(1) (2) (3) (4)						
005039	Albuterol Sulfate EQ 0.083% Base, Solution, Inhalation, 3 ml	0.1990 0.1450 0.1150	Jun 1997 Apr 2001 05/08/05	10/01/97 01/22/02 05/08/05	12/06/00 05/07/05 05/08/05	None Too High Too High
(5) (6) (7)						
048262	Cefadroxil 500 mg, Capsule, Oral, 50	2.7672 3.0789 2.4837	Oct 1996 Apr 2001 03/11/03	01/01/97 01/22/02 01/22/02	08/31/98 03/10/03 03/11/03	Invalid Price Too High None
(8) (9) (10)						
004560	Clonazepam 0.5 mg, Tablet, Oral, 100	0.8702 0.4146 0.2760 0.2455	Jun 1997 Apr 1998 Jan 2000 Apr 2001	10/01/97 09/01/98 12/07/00 01/22/02	08/31/98 12/06/00 01/21/02 01/22/02	Too High Too Low Too High Too High
(11) (12) (13) (14)						
000386	Enalapril Maleate 20 mg, Tablet, Oral, 100	0.9150		08/24/03		Too High
(15)						
017297	Isosorbide MN 60 mg, Tablet, Extended Release, Oral, 100	0.7492 0.2025	Apr 2001	01/22/02 07/21/05	07/20/05	Too Low Too Low
(16) (17)						
003758	Lorazepam 1 mg, Tablet, Oral, 100	0.0207 0.0203 0.6684 0.5718	Jan 1994 Jun 1997 Apr 1998 Jan 2000	07/01/94 10/01/97 09/01/98 12/07/00	09/30/97 02/11/98 12/06/00 12/07/00	Too High Too High Too High Too High
(18) (19) (20) (21)						
005131	Metoprolol 100 mg, Tablet, Oral, 100	0.1185 0.1161 0.0878 0.1290 0.0914 0.0690	Oct 1996 Jun 1997 Apr 1998 Jan 2000 Apr 2001 10/28/04	01/01/97 10/01/97 09/01/98 12/07/00 01/22/02 01/22/02	09/30/97 08/31/98 12/06/00 01/21/02 10/27/04 None	Too High Too High Too High Too High Too High None
(22) (23) (24) (25) (26) (27)						
011673	Ranitidine EQ 150 mg Base, Tablet, Oral, 100	0.5914 0.3410 0.3411 0.1088		09/24/98 12/07/00 01/22/02 05/08/05	09/21/99 01/21/02 05/07/05 05/08/05	Too High Too High Too High None
(28) (29) (30) (31)						

Notes: - For information on the descriptions and dates for the FULs provided and relevant sources, see notes and sources to Exhibits 3-5 of the Addanki Report.  
- Periods where no FUL was available are not listed separately.

<sup>1</sup> For "Too High" see Exhibit 3; for "Too Low" see Exhibit 4; for "Invalid Price" see note 13 to Exhibit 5 of the Addanki Report. See also Gaston Declaration, Paragraph 5.

Sources: - Declaration of Susan E. Gaston, In re: Pharmaceutical Industry Average Wholesale Price Litigation relating to The City of New York, et al. v. Abbott Laboratories, Inc., et al., June 15, 2009 ("Gaston Declaration").  
- Expert Report of Dr. Sumanth Addanki, In re: Pharmaceutical Industry Average Wholesale Price Litigation relating to The City of New York, et al. v. Abbott Laboratories, Inc et al., March 18, 2009 ("Addanki Report").

## Exhibit 6

Share of Total Units Reimbursed by Medicaid Nationally for Clonazepam 0.5 mg Tablet (GCN 004560)<sup>1</sup>  
 FUL: \$0.2760, Effective 12/07/00 to 01/21/02, Set Using a Package Size of 100 and Data Current as of January 2000<sup>2</sup>  
 1999q1 - 2001q4

Implied FUL <sup>4</sup>	Published WAC <sup>5</sup>	Package Size <sup>6</sup>	NDC	Red Book Company Name <sup>7</sup>	(Percent)														
					1999q1	1999q2	1999q3	1999q4	2000q1	2000q2	2000q3	2000q4	2001q1	2001q2	2001q3	2001q4			
(a)	(b)	(c)	(d)	(e)	(f)	(g)	(h)	(i)	(j)	(k)	(l)	(m)	(n)	(o)	(p)	(q)			
					%	%	%	%	0.0 %	0.0 %	0.0 %	0.0 %	0.0 %	0.0 %	0.0 %	0.0 %			
	0.5179	28	64019010503	Vangard Labs, Inc.					0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0			
		30	00615045665														0.0		
	0.5179	56	64019010506														0.0		
	0.6403	90	60429052490	Golden State Med. Supply, Inc.	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0		
0.1397; 0.1484	0.0931	100	00093083201	Teva Pharmaceuticals USA	56.2	54.1	52.2	49.5	48.1	45.8	43.6	42.4	42.4	41.8	41.1	40.0			
0.2003	0.1335	100	55953002740	Teva Pharmaceuticals USA		0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.1	0.0	0.0	0.0	0.0		
0.2453	0.1635	100	55953002741	Teva Pharmaceuticals USA			0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0		
0.2607	0.1738	100	51079088120	UDL Laboratories, Inc.	0.3	0.3	0.3	0.4	0.3	0.4	0.3	0.4	0.5	0.5	0.4	0.4	0.4		
0.2661	0.1774	100	51079088121	UDL Laboratories, Inc.	0.0	0.1	0.1	0.1	0.1	0.1	0.1	0.1	0.1	0.1	0.1	0.1	0.1		
0.2760	0.1840	100	00378191001	Mylan Pharmaceuticals, Inc.	0.0	0.1	0.1	0.2	0.3	0.6	1.0	1.0	1.3	1.7	1.9	2.2			
	0.2046	100	00228300311	Actavis Elizabeth LLC	16.3	15.8	16.2	16.2	16.6	16.8	17.0	16.7	16.6	16.8	16.7	16.7	16.7		
	0.2414	100	00904534260	Major Pharmaceuticals		0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0		
	0.5699	100	62269035324	Geneva Pharmaceuticals, Inc.	2.2	2.5	2.6	2.4	1.9	2.0	1.9	1.9	1.7	1.6	1.2	0.7			
0.6321 <sup>8</sup>	100	00004006801	Roche Laboratories	7.1	6.5	5.0	5.0	4.8	3.8	3.6	3.6	3.5	3.5	3.4	3.4	3.3			
0.6321 <sup>9</sup>	100	00004006845	Roche Laboratories*	0.0	0.0	0.0			0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0		
	100	00004006850	Roche Laboratories	0.2	0.1	0.1	0.1	0.1	0.0	0.1	0.0	0.1	0.0	0.1	0.0	0.0	0.0		
	100	00185006301	Sandoz	1.6	1.6	1.5	1.6	1.6	1.5	1.4	1.4	1.4	1.3	1.3	1.5	1.8			
	100	498844049501	Par Pharmaceutical, Inc.		0.0	0.0	0.1	0.1	0.5	1.4	1.8	2.1	1.9	0.1	0.1	0.1	0.1		
	100	52544074601	Watson Pharma, Inc.*	1.7	2.0	3.0	3.9	4.2	4.8	5.0	4.6	4.1	5.3	5.7	5.5				
	100	62037095201	Andrx Pharmaceuticals, Inc.	0.6	0.8	0.8	0.9	0.8	0.6	0.6	0.5	0.5	0.4	0.3	0.2				
	310	00615045653	Vangard Labs, Inc.	0.1	0.2	0.3	0.2	0.2	0.2	0.3	0.3	0.1	0.1	0.2	0.2				
	310	00615045663	Vangard Labs, Inc.	0.3	0.4	0.3	0.4	0.3	0.4	0.3	0.3	0.1	0.1	0.1	0.1				
0.0885	500	00093083205	Teva Pharmaceuticals USA	1.0	1.3	1.9	2.0	2.3	2.5	2.7	2.9	3.0	3.9	4.4	4.4				
0.1268	500	55953002770	Teva Pharmaceuticals USA		0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0		
0.1805	500	00228300350	Actavis Elizabeth LLC	5.2	6.3	6.4	7.2	7.4	7.2	7.5	7.7	8.2	8.7	8.8	9.4				
0.2199	500	00904534240	Major Pharmaceuticals					0.0	0.0	0.0	0.1	0.1	0.1	0.2	0.1				
0.5258	500	62269035329	Geneva Pharmaceuticals, Inc.	0.5	0.7	0.9	1.2	1.3	1.4	1.5	1.6	1.5	1.6	1.3	0.7				
	500	00185006305	Sandoz	2.3	2.0	2.1	2.0	1.6	1.5	1.2	1.4	1.3	1.3	1.4	2.1				
	500	52544074605	Watson Pharma, Inc.*	0.1	0.3	0.5	0.6	0.7	1.4	1.7	1.8	1.9	2.0	2.4	2.6				
	500	62037095205	Andrx Pharmaceuticals, Inc.	1.8	2.2	2.4	2.4	2.4	2.8	3.1	3.2	3.2	2.1	1.6	1.9				
	750	63739026301	McKesson Packaging Services				0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.1	0.1		
	750	63739026303	McKesson Packaging Services					0.1	0.1	0.1	0.1	0.1	0.1	0.1	0.1	0.1	0.1		
0.0838	1,000	00093083210	Teva Pharmaceuticals USA	0.8	1.4	1.7	2.0	2.3	2.6	2.7	3.0	3.3	3.4	3.2	3.1				
0.1202	1,000	55953002780	Teva Pharmaceuticals USA				0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0		
0.1750	1,000	00378191010	Mylan Pharmaceuticals, Inc.	0.0	0.0	0.0	0.2	0.4	0.7	1.1	1.3	1.7	1.9	2.2	2.7				
	1,000	00185006310	Sandoz	1.6	1.3	1.5	1.5	1.5	1.5	1.4	1.5	1.5	1.5	1.5	1.6	1.6			
	1,000	00615045643	Vangard Labs, Inc.	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0		

Total: 100.0 % 100.0 % 100.0 % 100.0 % 100.0 % 100.0 % 100.0 % 100.0 % 100.0 % 100.0 % 100.0 % 100.0 % 100.0 % 100.0 % 100.0 % 100.0 % 100.0 %

Notes: - Shares are displayed rounded to one decimal. Hence, values of "0.0" correspond to NDCs for which the quarterly share was less than 0.05 percent. Missing values correspond to quarters for which Medicaid reimbursement was not reported in the CMS data

**Exhibit 6**

**Share of Total Units Reimbursed by Medicaid Nationally for Clonazepam 0.5 mg Tablet (GCN 004560)<sup>1</sup>**  
**FUL: \$0.2760, Effective 12/07/00 to 01/21/02, Set Using a Package Size of 100 and Data Current as of January 2000<sup>2</sup>**  
**1999q1 - 2001q4**

for the specified NDC.

- Table includes all NDCs identified as belonging to the GCN (see Note 1) for which Medicaid reimbursement was reported by CMS for the selected period.

<sup>1</sup> Shares are calculated as the total units reimbursed nationally by Medicaid for the specified NDC relative to the total units reimbursed across all NDCs identified as belonging to the GCN. NDCs identified as belonging to the GCN include: (1) products explicitly identified by the First DataBank ("FDB") variable "GCN Sequence Number" as belonging to the GCN; (2) any similarly described products (based on name, strength, and dosage form) not listed in FDB that appear in Medispan or Red Book and not exclusively in another GCN in FDB at the NDC-9 level. Finally, following a review of online sources for NDCs that do not appear in FDB at the NDC-11 or NDC-9 level (355 NDCs in total, across all 9 GCNs), seven NDCs were dropped from the analysis (52493084701, 52493084717, 54977069501, 54977070601, 57362011601, 63874074917, and 51655027924), as either they were described as albuterol inhaler refills and not as albuterol inhalers or discrepancies in their descriptions were resolved such that they were confirmed to be outside the GCN.

<sup>2</sup> The FUL, the month during which data used to set the FUL was current (i.e., the "current month"), the package size used to set the FUL, and the beginning of the FUL effective period are based on data reported in the CMS transmittals. The end of the FUL effective period is based on data reported in FDB and Red Book.

<sup>3</sup> Lower than and matching candidates are based on published compendia prices tabulated in Exhibits 3 and 5, respectively, of the Report of Dr. Sumanth Addanki. Selected candidates correspond to the narrowest set of requirements (i.e., therapeutic equivalence and package size) for which published compendia prices were identified in Exhibits 3 and 5. Records for which multiple NDCs are identified correspond to instances where lower than or matching candidates with reimbursement during the relevant period are reported for two or more NDCs corresponding to the same product, as occurs when the NDC for a product changes.

<sup>4</sup> The implied FUL is calculated by multiplying the published compendia price by 1.5 and rounding to four decimals. The implied FUL is only populated for NDCs identified as matching or lower than candidates.

<sup>5</sup> The "Published WAC", which is displayed rounded to four decimals, is based on compendia WACs reported by Medispan, FDB, and Red Book. Unless noted otherwise, WACs must be active (i.e., the price has not been deactivated by obsolescence, a subsequent price posting, or otherwise) for the entire current month. NDCs with multiple WACs listed correspond to products for which different WACs were reported by the compendia. NDCs with a missing WAC correspond to products for which there was no active WAC at any point during the current month. Obsolescence, generally, is determined with reference to the FDB "Obsolete Date", the FDB "HCFA Termination Date", the Medispan "Inactive Date", and the Red Book "NDC Discontinuation Date" (collectively, the "end dates"). WACs are only analyzed during the period prior to the earliest of the four end dates. However, any postings on or after the earliest end date are treated as a reactivation of the NDC and such postings are analyzed until the next end date. Postings after the second, third, or fourth end date are treated in the same manner. Similarly, the Red Book "Reactivation Date" can reactivate the most recent set of active prices for an NDC, assuming the date falls on or after the discontinuation date and the NDC is not already currently active. Finally, 33 NDCs among all nine GCNs, for which the FDB Obsolete Date exhibited stark inconsistencies across annual files, were examined separately, using price posting activity and CMS reimbursement.

<sup>6</sup> The package size is based on the FDB variable "Package Size". If unavailable, the package size is based on the most common value observed across the Medispan implied package size (the mean ratio between the package and unit prices, rounded to one decimal) and the Red Book variables "Total Quantity - Actual" and "Standard Quantity - Actual".

<sup>7</sup> Company names with an asterisk correspond to NDCs for which Red Book data are unavailable. In such instances the company name is based on NDCs with the same labeler code.

<sup>8</sup> The specified WAC was only active for part of the current month. A WAC of \$0.61660 was posted by all three pricing compendia on January 14, 1998 and was replaced with a WAC of \$0.63210 on January 19, 2000.

<sup>9</sup> The specified WAC was only active for part of the current month. A WAC of \$0.61660 was posted by FDB on January 14, 1998 and was replaced with a WAC of \$0.63210 on January 19, 2000.

Sources: - American Medical Association, *AMA Downloadable Resource Table: Asthma*, ASTHMA Version 3.0 July 2007, <[http://www.ama-assn.org/ama1/pub/upload/mm/370/astcodingspecs307\\_7.xls](http://www.ama-assn.org/ama1/pub/upload/mm/370/astcodingspecs307_7.xls)>.

- "Comprehensive Price History File," 2007 Wolters Kluwer Health (Medispan).

- Department of Health and Human Services, Health Care Financing Administration, "State Medicaid Manual: Part 6 - Payment for Services," Transmittal No. 36 (November 2000).

- First DataBank (Alabama Production) Data and *NDDF (National Drug Data File)™ Documentation Manual* (Rev. April 2000).

- FloridaInfusion, Nations Drug, Accessed February 6, 2009 <<http://www.floridainfusion.com/awps.asp?keyword=capoten&searchfield=keyword>>.

- Medicaid State Drug Utilization Data including "Definitions for State Drug Utilization Data Specifications", Centers for Medicare & Medicaid Services.

- Medispan Inactive Dates, 2007 Wolters Kluwer Health (Medispan).

- Red Book Advanced Data and *Red Book™ Drug Products and Pricing Developer's Guide Advanced* (January 2008).

- U.S. Food and Drug Administration, Center for Drug Evaluation and Research, *Approved Drug Products with Therapeutic Equivalence Evaluations*, 11th Edition - 27th Edition.

- U.S. Food and Drug Administration, Center for Drug Evaluation and Research, *National Drug Code Directory*, <<http://www.fda.gov/cder/ndc/database/>>.

## Exhibit 7

Share of Total Units Reimbursed by Medicaid Nationally for Clonazepam 0.5 mg Tablet (GCN 004560)<sup>1</sup>  
 FUL: \$0.2455, Effective 01/22/02 to at Least 06/09/08, Set Using a Package Size of 100 and Data Current as of April 2001<sup>2</sup>  
 2000q1 - 2002q4

Implied FUL <sup>4</sup>	Published WAC <sup>5</sup>	Package Size <sup>6</sup>	NDC	Red Book Company Name <sup>7</sup>	(Percent)											
					2000q1	2000q2	2000q3	2000q4	2001q1	2001q2	2001q3	2001q4	2002q1	2002q2	2002q3	2002q4
(a)	(b)	(c)	(d)	(e)	(f)	(g)	(h)	(i)	(j)	(k)	(l)	(m)	(n)	(o)	(p)	(q)
0.5179	28	64019010503		Vanguard Labs, Inc.	0.0	0.0 %	0.0	0.0 %	0.0	0.0 %	0.0	0.0 %	0.0	0.0 %	0.0	0.0 %
	30	00615045665														
0.5179	56	64019010506														
0.2111; 0.6403	90	60429052490		Golden State Med. Supply, Inc.	0.0											
0.1199	0.0799	100	00904534260	Major Pharmaceuticals	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
0.1397; 0.1484	0.0931	100	00093083201	Teva Pharmaceuticals USA	48.1	45.8	43.6	42.4	42.4	41.8	41.1	40.0	38.6	36.9	35.7	35.4
0.1335 <sup>8</sup>	100	55953002740		Teva Pharmaceuticals USA	0.0	0.0	0.0	0.1	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
0.2453	0.1635	100	55953002741	Teva Pharmaceuticals USA	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
0.2456	0.1637	100	00228300311	Actavis Elizabeth LLC	16.6	16.8	17.0	16.7	16.6	16.8	16.7	16.7	16.8	17.2	16.7	11.3
0.1738	100	51079088120		UDL Laboratories, Inc.	0.3	0.4	0.3	0.4	0.5	0.4	0.4	0.4	0.4	0.4	0.3	0.4
0.1774	100	51079088121		UDL Laboratories, Inc.	0.1	0.1	0.1	0.1	0.1	0.1	0.1	0.1	0.1	0.1	0.1	0.1
0.1840	100	00378191001		Mylan Pharmaceuticals, Inc.	0.3	0.6	1.0	1.0	1.3	1.7	1.9	2.2	2.7	3.3	3.2	3.1
0.1841	100	49884049501		Par Pharmaceutical, Inc.	0.5	1.4	1.8	2.1	1.9	0.3	0.1	0.1	0.0	0.1	0.0	0.1
0.2018	100	00591074601		Watson Labs										0.1	2.1	4.1
0.7064	100	00004006801		Roche Laboratories	4.8	3.8	3.6	3.6	3.5	3.4	3.4	3.3	2.8	2.7	2.6	1.9
0.7064	100	00004006845		Roche Laboratories*		0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
	100	00004006850		Roche Laboratories	0.1	0.0	0.1	0.0	0.1	0.1	0.0	0.0	0.0	0.0	0.0	0.0
	100	00185006301		Sandoz	1.6	1.5	1.4	1.4	1.3	1.3	1.5	1.8	1.7	1.7	1.5	2.3
	100	52544074601		Watson Pharma, Inc.*	4.2	4.8	5.0	4.6	4.1	5.3	5.7	5.5	5.9	3.3	1.6	0.6
	100	57664027308		Caraco Pharm. Labs., Ltd.									0.0	0.1	0.1	0.2
	100	62037095201		Andrx Pharmaceuticals, Inc.	0.8	0.6	0.6	0.5	0.5	0.4	0.3	0.2	0.3	0.3	0.2	0.2
	100	62269035324		Geneva Pharmaceuticals, Inc.	1.9	2.0	1.9	1.9	1.7	1.6	1.2	0.7	0.5	0.3	0.2	0.1
	310	00615045653		Vanguard Labs, Inc.	0.2	0.2	0.3	0.3	0.1	0.1	0.2	0.2	0.3	0.2	0.1	0.1
	310	00615045663		Vanguard Labs, Inc.	0.3	0.4	0.3	0.3	0.1	0.1	0.1	0.1	0.1	0.1	0.1	0.1
0.0660	500	00904534240		Major Pharmaceuticals	0.0	0.0	0.0	0.1	0.1	0.1	0.2	0.1	0.1	0.1	0.1	0.2
0.0885	500	00093083205		Teva Pharmaceuticals USA	2.3	2.5	2.7	2.9	3.0	3.9	4.4	4.4	4.3	4.2	4.3	5.0
0.1268 <sup>9</sup>	500	55953002770		Teva Pharmaceuticals USA	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
0.1637	500	00228300350		Actavis Elizabeth LLC	7.4	7.2	7.5	7.7	8.2	8.7	8.8	9.4	9.4	9.7	10.3	15.5
0.1917	500	00591074605		Watson Labs										0.4	1.8	2.4
0.1917	500	52544074605		Watson Pharma, Inc.*	0.7	1.4	1.7	1.8	1.9	2.0	2.4	2.6	2.9	3.0	2.2	1.3
0.5258	500	62269035329		Geneva Pharmaceuticals, Inc.	1.3	1.4	1.5	1.6	1.5	1.6	1.3	0.7	0.5	0.3	0.3	0.2
	500	00185006305		Sandoz	1.6	1.3	1.2	1.4	1.3	1.3	1.4	2.1	2.4	2.2	1.7	2.3
	500	57664027313		Caraco Pharm. Labs., Ltd.										0.0	0.1	0.4
	500	62037095205		Andrx Pharmaceuticals, Inc.	2.4	2.8	3.1	3.2	3.2	2.1	1.6	1.9	1.9	2.1	2.0	1.3
	750	63739026301		McKesson Packaging Services	0.0	0.0	0.0	0.0	0.0	0.0	0.1	0.1	0.1	0.1	0.1	0.1
	750	63739026303		McKesson Packaging Services	0.1	0.1	0.1	0.1	0.1	0.1	0.1	0.1	0.2	0.2	0.2	0.2
0.0838	1,000	00093083210		Teva Pharmaceuticals USA	2.3	2.6	2.7	3.0	3.3	3.4	3.2	3.1	3.1	3.2	3.7	3.9
0.1202	1,000	55953002780		Teva Pharmaceuticals USA	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
0.1750	1,000	00378191010		Mylan Pharmaceuticals, Inc.	0.4	0.7	1.1	1.3	1.7	1.9	2.2	2.7	3.3	4.1	4.4	4.1
	1,000	00185006310		Sandoz	1.5	1.5	1.4	1.5	1.5	1.5	1.5	1.6	1.7	1.8	1.9	2.1
	1,000	00615045643		Vanguard Labs, Inc.	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.3	0.8
	1,000	57664027318		Caraco Pharm. Labs., Ltd.									0.0	0.3	0.8	
<b>Total:</b>					<b>100.0</b>	<b>%</b>										

**Exhibit 7**

**Share of Total Units Reimbursed by Medicaid Nationally for Clonazepam 0.5 mg Tablet (GCN 004560)<sup>1</sup>**  
**FUL: \$0.2455, Effective 01/22/02 to at Least 06/09/08, Set Using a Package Size of 100 and Data Current as of April 2001<sup>2</sup>**  
**2000q1 - 2002q4**

Notes: - Shares are displayed rounded to one decimal. Hence, values of "0.0" correspond to NDCs for which the quarterly share was less than 0.05 percent. Missing values correspond to quarters for which Medicaid reimbursement was not reported in the CMS data for the specified NDC.  
- Table includes all NDCs identified as belonging to the GCN (see Note 1) for which Medicaid reimbursement was reported by CMS for the selected period.

<sup>1</sup> Shares are calculated as the total units reimbursed nationally by Medicaid for the specified NDC relative to the total units reimbursed across all NDCs identified as belonging to the GCN. NDCs identified as belonging to the GCN include: (1) products explicitly identified by the First DataBank ("FDB") variable "GCN Sequence Number" as belonging to the GCN; (2) any similarly described products (based on name, strength, and dosage form) not listed in FDB that appear in Medispan or Red Book and not exclusively in another GCN in FDB at the NDC-9 level. Finally, following a review of online sources for NDCs that do not appear in FDB at the NDC-11 or NDC-9 level (355 NDCs in total, across all 9 GCNs), seven NDCs were dropped from the analysis (52493084701, 52493084717, 54977069501, 54977070601, 57362011601, 63874074917, and 51655027924), as either they were described as albuterol inhaler refills and not as albuterol inhalers or discrepancies in their descriptions were resolved such that they were confirmed to be outside the GCN.

<sup>2</sup> The FUL, the month during which data used to set the FUL was current (i.e., the "current month"), the package size used to set the FUL, and the beginning of the FUL effective period are based on data reported in the CMS transmittals. The end of the FUL effective period is based on data reported in FDB and Red Book.

<sup>3</sup> Lower than and matching candidates are based on published compendia prices tabulated in Exhibits 3 and 5, respectively, of the Report of Dr. Sumanth Addanki. Selected candidates correspond to the narrowest set of requirements (i.e., therapeutic equivalence and package size) for which published compendia prices were identified in Exhibits 3 and 5. Records for which multiple NDCs are identified correspond to instances where lower than or matching candidates with reimbursement during the relevant period are reported for two or more NDCs corresponding to the same product, as occurs when the NDC for a product changes.

<sup>4</sup> The implied FUL is calculated by multiplying the published compendia price by 1.5 and rounding to four decimals. The implied FUL is only populated for NDCs identified as matching or lower than candidates.

<sup>5</sup> The "Published WAC", which is displayed rounded to four decimals, is based on compendia WACs reported by Medispan, FDB, and Red Book. Unless noted otherwise, WACs must be active (i.e., the price has not been deactivated by obsolescence, a subsequent price posting, or otherwise) for the entire current month. NDCs with multiple WACs listed correspond to products for which different WACs were reported by the compendia. NDCs with a missing WAC correspond to products for which there was no active WAC at any point during the current month. Obsolescence, generally, is determined with reference to the FDB "Obsolete Date", the FDB "HCFA Termination Date", the Medispan "Inactive Date", and the Red Book "NDC Discontinuation Date" (collectively, the "end dates"). WACs are only analyzed during the period prior to the earliest of the four end dates. However, any postings on or after the earliest end date are treated as a reactivation of the NDC and such postings are analyzed until the next end date. Postings after the second, third, or fourth end date are treated in the same manner. Similarly, the Red Book "Reactivation Date" can reactivate the most recent set of active prices for an NDC, assuming the date falls on or after the discontinuation date and the NDC is not already currently active. Finally, 33 NDCs among all nine GCNs, for which the FDB Obsolete Date exhibited stark inconsistencies across annual files, were examined separately, using price posting activity and CMS reimbursement.

<sup>6</sup> The package size is based on the FDB variable "Package Size". If unavailable, the package size is based on the most common value observed across the Medispan implied package size (the mean ratio between the package and unit prices, rounded to one decimal) and the Red Book variables "Total Quantity - Actual" and "Standard Quantity - Actual".

<sup>7</sup> Company names with an asterisk correspond to NDCs for which Red Book data are unavailable. In such instances the company name is based on NDCs with the same labeler code.

<sup>8</sup> The specified WAC was only active for part of the current month, as the NDC was declared inactive by Medispan and obsolete by FDB on April 4, 2001, and reported as discontinued by Red Book on April 9, 2001.

<sup>9</sup> The specified WAC was only active for part of the current month, as the NDC was reported as discontinued by Red Book on April 30, 2001.

- Sources:
- American Medical Association, *AMA Downloadable Resource Table: Asthma*, ASTHMA Version 3.0 July 2007, <[http://www.ama-assn.org/ama1/pub/upload/mm/370/astcodingspecs307\\_7.xls](http://www.ama-assn.org/ama1/pub/upload/mm/370/astcodingspecs307_7.xls)>.
  - "Comprehensive Price History File," 2007 Wolters Kluwer Health (Medispan).
  - Department of Health and Human Services, Health Care Financing Administration, "State Medicaid Manual: Part 6 - Payment for Services," Transmittal No. 37 (November 2001).
  - First DataBank (Alabama Production) Data and *NDDF (National Drug Data File)™ Documentation Manual* (Rev. April 2000).
  - FloridaInfusion, Nations Drug, Accessed February 6, 2009 <<http://www.floridainfusion.com/awps.asp?keyword=capoten&searchfield=keyword>>.
  - Medicaid State Drug Utilization Data including "Definitions for State Drug Utilization Data Specifications", Centers for Medicare & Medicaid Services.
  - Medispan Inactive Dates, 2007 Wolters Kluwer Health (Medispan).
  - Red Book Advanced Data and *Red Book™ Drug Products and Pricing Developer's Guide Advanced* (January 2008).
  - U.S. Food and Drug Administration, Center for Drug Evaluation and Research, *Approved Drug Products with Therapeutic Equivalence Evaluations*, 11th Edition - 27th Edition.
  - U.S. Food and Drug Administration, Center for Drug Evaluation and Research, *National Drug Code Directory*, <<http://www.fda.gov/cder/ndc/database/>>.

## Exhibit 8

**Share of Total Units Reimbursed by Medicaid Nationally for Metoprolol 100 mg Tablet (GCN 005131)<sup>1</sup>**  
**FUL: \$0.0914, Effective 01/22/02 to 10/27/04, Set Using a Package Size of 100 and Data Current as of April 2001<sup>2</sup>**  
**2000q1 - 2002q4**

  "TE&PS" Lower Than Candidates<sup>3</sup>  
  "TE&PS" Matching Candidates<sup>3</sup>

Implied FUL <sup>4</sup>	Published WAC <sup>5</sup>	Package Size <sup>6</sup>	NDC	Red Book Company Name <sup>7</sup>	(Percent)																
					2000q1	2000q2	2000q3	2000q4	2001q1	2001q2	2001q3	2001q4	2002q1	2002q2	2002q3	2002q4					
(a)	(b)	(c)	(d)	(e)	(f)	(g)	(h)	(i)	(j)	(k)	(l)	(m)	(n)	(o)	(p)	(q)					
					%	0.0 %	0.0 %	%	%	%	0.0 %	0.0 %	0.0 %	0.0 %	0.0 %	0.0 %	0.0 %	0.0 %			
0.0690	0.0460	100	00591046301	UDL Laboratories, Inc.													0.3	0.8	1.0		
0.0816	0.0544	100	00781122801	Sandoz	8.9	9.1	9.2	8.7	9.3	9.5	8.7	6.6	4.0	2.8	2.1	1.9					
0.0816	0.0544	100	00781137201	Geneva Pharmaceuticals, Inc.	6.6	5.3	4.2	3.9	3.3	2.3	1.9	1.6	1.2	1.0	0.4	0.1					
0.0854	0.0569	100	57664016708	Caraco Pharm. Labs., Ltd.	0.8	1.0	1.1	1.0	0.9	0.9	1.2	1.5	2.0	2.6	3.0	3.6					
0.0914	0.0609	100	53489036701	Mutual Pharm. Co., Inc.	2.1	2.0	2.4	2.4	2.3	2.3	2.5	2.6	2.7	2.6	2.7	2.8					
	0.0618	100	00904794760	Major Pharmaceuticals	0.1	0.1	0.1	0.1	0.1	0.1	0.1	0.1	0.1	0.1	0.1	0.1	0.1	0.1	0.1		
	0.0725	100	00378004701	Mylan Pharmaceuticals, Inc.	23.9	24.5	24.8	25.7	25.9	25.9	26.1	26.9	28.0	28.0	27.0	25.9					
0.0914	0.0609; 0.0860	100	00677148301	United Research Labs, Inc.	0.8	0.7	0.7	0.7	0.6	0.6	0.6	0.7	0.7	0.7	0.7	0.7	0.7	0.7			
	0.0988 <sup>8</sup>	100	00093073401	Teva Pharmaceuticals USA	4.5	4.4	3.9	3.7	4.5	4.6	4.9	7.1	11.7	13.3	14.8	15.7					
	0.1133	100	51079080220	UDL Laboratories, Inc.	0.7	1.0	1.0	1.0	0.9	1.0	1.0	1.1	1.2	1.1	1.1	1.2					
	0.1213	100	57480080301	Medirex, Inc.	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0						
	0.1560 <sup>9</sup>	100	55953073440	Teva Pharmaceuticals USA	4.2	4.3	4.0	3.6	2.6	2.1	1.6	1.3	0.9	0.7	0.6	0.5					
	0.1695	100	00904777361	Major Pharmaceuticals	0.0	0.0	0.0	0.0	0.0	0.0	0.1	0.0	0.1	0.0	0.0	0.0	0.0	0.0	0.0		
0.3180; 0.3562	100	00781122813	Geneva Pharmaceuticals, Inc.	0.1	0.1	0.1	0.1	0.2	0.2	0.2	0.2	0.2	0.2	0.2	0.2	0.2	0.1	0.0	0.0		
	0.5232	100	59772369302	Geneva Pharmaceuticals, Inc.	6.2	6.2	6.4	6.3	6.0	6.3	6.6	5.2	2.1	1.4	1.1	0.8					
	0.9605	100	00028007101	Novartis Pharm	2.4	2.1	1.9	1.8	1.7	1.7	1.6	1.5	1.3	1.2	1.1	0.9					
	1.0081	100	00028007161	Novartis Pharm	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0		
	100	00028007165	Novartis Pharm	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0			
	100	00047095524	Warner Chilcott, Gen Prods Div	0.0												0.0	0.0				
	100	00182196701	Ivax Pharmaceuticals, Inc.	0.1	0.0	0.0	0.0	0.0													
	100	00182198801	Ivax Pharmaceuticals, Inc.	0.1	0.1	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0								
	100	00228255510	Purepac Pharmaceutical Co.	0.1	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0								
	100	00364256101	Schein Pharmaceutical, Inc.	0.2	0.1	0.1	0.1	0.1	0.0	0.0	0.0	0.0	0.0				0.0	0.0			
	100	00536560501	Rugby Laboratories, Inc.	0.1	0.1	0.1	0.1	0.1	0.1	0.1	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0			
	100	00536563901	Rugby Laboratories, Inc.	0.1	0.1	0.0	0.0	0.0	0.0	0.1	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0			
	100	00603462821	Qualitest Pharmaceuticals	0.4	0.4	0.3	0.3	0.3	0.3	0.2	0.2	0.2	0.2	0.2	0.2	0.2	0.2	0.2	0.1		
	100	00781137213	Geneva Pharmaceuticals, Inc.	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0			
	100	00904777360	Major Pharmaceuticals	0.1	0.1	0.2	0.1	0.1	0.1	0.1	0.1	0.1	0.1	0.1	0.1	0.1	0.1	0.0	0.0		
	100	00904782160	Major Pharmaceuticals	0.0	0.0	0.0											0.0	0.0			
	100	49884041301	Par Pharmaceutical, Inc.	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0			
	100	50111085601	Sidmak Laboratories Inc.	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0			
	100	50752030905	Geneva Pharmaceuticals, Inc.																		
	100	52544046301	Watson Pharma, Inc.*	1.1	1.3	1.5	1.6	1.5	1.7	1.8	1.6	1.4	1.2	0.8	0.5						
	100	52555050001	Martec Pharmaceutical, Inc.	0.0																	
	100	62939222101	Brightstone Pharma Inc.	0.0	0.0																
	100	64376050301	Boca Pharmacal, Inc.	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0			
	310	00615355353	Vanguard Labs, Inc.																		
	310	00615355363	Vanguard Labs, Inc.																		
	500	00228255550	Purepac Pharmaceutical Co.	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0			
	500	55953073470	Teva Pharmaceuticals USA	0.6	0.5	0.5	0.6	0.4	0.3	0.2	0.1	0.1	0.1	0.1	0.1	0.1	0.1	0.1	0.1		
	750	63739017401	McKesson Packaging Services	0.0	0.0	0.0	0.1	0.1	0.1	0.1	0.1	0.1	0.0	0.0	0.0	0.0	0.0	0.0	0.0		
	750	63739017403	McKesson Packaging Services														0.3	0.0	0.0		

## Exhibit 8

**Share of Total Units Reimbursed by Medicaid Nationally for Metoprolol 100 mg Tablet (GCN 005131)<sup>1</sup>**  
**FUL: \$0.0914, Effective 01/22/02 to 10/27/04, Set Using a Package Size of 100 and Data Current as of April 2001<sup>2</sup>**  
**2000q1 - 2002q4**

"TE&PS" Lower Than Candidates<sup>3</sup>  
 "TE&PS" Matching Candidates<sup>3</sup>

Implied FUL <sup>4</sup>	Published WAC <sup>5</sup>	Package Size <sup>6</sup>	NDC	Red Book Company Name <sup>7</sup>	(Percent)													
					2000q1	2000q2	2000q3	2000q4	2001q1	2001q2	2001q3	2001q4	2002q1	2002q2	2002q3	2002q4		
(a)	(b)	(c)	(d)	(e)	(f)	(g)	(h)	(i)	(j)	(k)	(l)	(m)	(n)	(o)	(p)	(q)		
0.0394	1.000	00591046310	Watson Labs												0.0	0.4	0.5	
0.0474	1.000	00781122810	Sandoz	5.3	5.7	6.2	6.7	7.7	8.5	8.2	5.4	3.6	2.6	2.2	1.6			
0.0474	1.000	00781137210	Geneva Pharmaceuticals, Inc.	1.1	0.7	0.7	0.6	0.6	0.4	0.3	0.2	0.1	0.1	0.0	0.0			
0.0499	1.000	57664016718	Caraco Pharm. Labs., Ltd.	2.1	2.6	2.7	2.7	2.5	2.8	3.2	4.4	5.9	7.2	8.5	10.2			
0.0520	1.000	00904794780	Major Pharmaceuticals	0.2	0.2	0.3	0.2	0.2	0.1	0.1	0.2	0.2	0.2	0.2	0.2	0.3		
0.0535	1.000	53489036710	Mutual Pharm. Co., Inc.	1.1	1.1	1.2	1.2	1.3	1.4	1.5	1.6	1.7	1.6	1.5	1.6			
0.0625	1.000	00378004710	Mylan Pharmaceuticals, Inc.	6.9	8.7	10.0	10.6	10.9	11.4	12.2	13.0	13.9	14.3	14.5	13.3			
0.0535; 0.0791	1.000	00677148310	United Research Labs, Inc.	0.3	0.3	0.2	0.2	0.2	0.2	0.2	0.3	0.3	0.3	0.3	0.3	0.4		
0.0938 <sup>10</sup>	1.000	00093073410	Teva Pharmaceuticals USA	8.7	8.2	8.3	8.3	8.7	8.8	9.2	11.3	12.5	12.6	13.0	13.9			
0.5178	1.000	59772369305	Geneva Pharmaceuticals, Inc.	4.4	2.6	1.7	1.7	1.9	2.1	1.9	2.0	1.6	1.1	0.9	0.6			
0.9507	1.000	00028007110	Novartis Pharm	0.1	0.1	0.0	0.1	0.1	0.0	0.0	0.0	0.1	0.0	0.0	0.0			
		00182196710	Ivax Pharmaceuticals, Inc.															
		00182198810	Ivax Pharmaceuticals, Inc.	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0			
		00228255956	Purepac Pharmaceutical Co.	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0					
		00364256102	Schein Pharmaceutical, Inc.	0.0	0.0									0.0				
		00603462832	Qualitest Pharmaceuticals	0.2	0.2	0.2	0.2	0.1	0.1	0.1	0.1	0.1	0.1	0.1	0.1	0.1	0.0	
		00904777380	Major Pharmaceuticals	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0		
		00904782180	Major Pharmaceuticals	0.0									0.0					
		49884041310	Par Pharmaceutical, Inc.	0.0	0.0	0.0	0.0	0.0	0.0	0.0								
		50111085603	Sidmak Laboratories Inc.	0.0	0.0	0.0	0.0	0.0	0.0	0.0								
		52544046310	Watson Pharma, Inc.*	0.9	1.0	1.1	1.3	1.4	1.4	1.5	1.3	1.3	1.3	1.3	0.8	0.8	0.7	
		55953073480	Teva Pharmaceuticals USA	4.5	4.7	4.5	4.0	3.1	2.4	1.8	1.2	0.8	0.7	0.6	0.5			
		64376050310	Boca Pharmacal, Inc.	0.0	0.0	0.0	0.1	0.1	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	
				Total:	100.0	%	100.0	%	100.0	%	100.0	%	100.0	%	100.0	%	100.0	%

Notes: - Shares are displayed rounded to one decimal. Hence, values of "0.0" correspond to NDCs for which the quarterly share was less than 0.05 percent. Missing values correspond to quarters for which Medicaid reimbursement was not reported in the CMS data for the specified NDC.

- Table includes all NDCs identified as belonging to the GCN (see Note 1) for which Medicaid reimbursement was reported by CMS for the selected period.

<sup>1</sup> Shares are calculated as the total units reimbursed nationally by Medicaid for the specified NDC relative to the total units reimbursed across all NDCs identified as belonging to the GCN. NDCs identified as belonging to the GCN include: (1) products explicitly identified by the First DataBank ("FDB") variable "GCN Sequence Number" as belonging to the GCN; (2) any similarly described products (based on name, strength, and dosage form) not listed in FDB that appear in Medispan or Red Book and not exclusively in another GCN in FDB at the NDC-9 level. Finally, following a review of online sources for NDCs that do not appear in FDB at the NDC-11 or NDC-9 level (355 NDCs in total, across all 9 GCNs), seven NDCs were dropped from the analysis (52493084701, 52493084717, 54977069501, 54977070601, 57362011601, 63874074917, and 51655027924), as either they were described as albuterol inhaler refills and not as albuterol inhalers or discrepancies in their descriptions were resolved such that they were confirmed to be outside the GCN.

<sup>2</sup> The FUL, the month during which data used to set the FUL was current (i.e., the "current month"), the package size used to set the FUL, and the beginning of the FUL effective period are based on data reported in the CMS transmittals. The end of the FUL effective period is based on data reported in FDB and Red Book.

<sup>3</sup> Lower than and matching candidates are based on published compendia prices tabulated in Exhibits 3 and 5, respectively, of the Report of Dr. Sumanth Addanki. Selected candidates correspond to the narrowest set of requirements (i.e., therapeutic equivalence and package size) for which published compendia prices were identified in Exhibits 3 and 5. Records for which multiple NDCs are identified correspond to instances where lower than or matching candidates with reimbursement during the relevant period are reported for two or more NDCs corresponding to the same product, as occurs when the NDC for a product changes.

<sup>4</sup> The implied FUL is calculated by multiplying the published compendia price by 1.5 and rounding to four decimals. The implied FUL is only populated for NDCs identified as matching or lower than candidates.

<sup>5</sup> The "Published WAC", which is displayed rounded to four decimals, is based on compendia WACs reported by Medispan, FDB, and Red Book. Unless noted otherwise, WACs must be active (i.e., the price has not been deactivated by obsolescence,

**Exhibit 8**

**Share of Total Units Reimbursed by Medicaid Nationally for Metoprolol 100 mg Tablet (GCN 005131)<sup>1</sup>**  
**FUL: \$0.0914, Effective 01/22/02 to 10/27/04, Set Using a Package Size of 100 and Data Current as of April 2001<sup>2</sup>**  
**2000q1 - 2002q4**

"TE&PS" Lower Than Candidates<sup>3</sup>  
"TE&PS" Matching Candidates<sup>3</sup>

Implied FUL <sup>4</sup>	Published WAC <sup>5</sup>	Package Size <sup>6</sup>	NDC	Red Book Company Name <sup>7</sup>	2000q1	2000q2	2000q3	2000q4	2001q1	2001q2	2001q3	2001q4	2002q1	2002q2	2002q3	2002q4
(a)	(b)	(c)	(d)	(e)	(f)	(g)	(h)	(i)	(j)	(k)	(l)	(m)	(n)	(o)	(p)	(q)

a subsequent price posting, or otherwise) for the entire current month. NDCs with multiple WACs listed correspond to products for which different WACs were reported by the compendia. NDCs with a missing WAC correspond to products for which there was no active WAC at any point during the current month. Obsolescence, generally, is determined with reference to the FDB "Obsolete Date", the FDB "HCFA Termination Date", the Medispan "Inactive Date", and the Red Book "NDC Discontinuation Date" (collectively, the "end dates"). WACs are only analyzed during the period prior to the earliest of the four end dates. However, any postings on or after the earliest end date are treated as a reactivation of the NDC and such postings are analyzed until the next end date. Postings after the second, third, or fourth end date are treated in the same manner. Similarly, the Red Book "Reactivation Date" can reactivate the most recent set of active prices for an NDC, assuming the date falls on or after the discontinuation date and the NDC is not already currently active. Finally, 33 NDCs among all nine GCNs, for which the FDB Obsolete Date exhibited stark inconsistencies across annual files, were examined separately, using price posting activity and CMS reimbursement.

<sup>6</sup> The package size is based on the FDB variable "Package Size". If unavailable, the package size is based on the most common value observed across the Medispan implied package size (the mean ratio between the package and unit prices, rounded to one decimal) and the Red Book variables "Total Quantity - Actual" and "Standard Quantity - Actual".

<sup>7</sup> Company names with asterisk correspond to NDCs for which Red Book data are unavailable. In such instances the company name is based on NDCs with the same labeler code.

<sup>8</sup> The specified WAC was only active for part of the current month. A WAC of \$0.0980 was posted by FDB on August 11, 1995, and was replaced with a WAC of \$0.0790 on April 30, 2001. The latter WAC was also reported by Medispan, but not until April 30, 2001.

<sup>9</sup> The specified WAC was only active for part of the current month, as the NDC was declared inactive by Medispan and obsolete by FDB on April 4, 2001, and reported as discontinued by Red Book on April 9, 2001.

<sup>10</sup> The specified WAC was only active for part of the current month. A WAC of \$0.09382 was posted by FDB on August 11, 1995, and was replaced with a WAC of \$0.07250 on April 30, 2001. The latter WAC was also reported by Medispan, but not until April 30, 2001.

- Sources:
- American Medical Association, *AMA Downloadable Resource Table: Asthma*, ASTHMA Version 3.0 July 2007, <[http://www.ama-assn.org/ama1/pub/upload/mm/370/astcodingspecs307\\_7.xls](http://www.ama-assn.org/ama1/pub/upload/mm/370/astcodingspecs307_7.xls)>.
  - "Comprehensive Price History File," 2007 Wolters Kluwer Health (Medispan).
  - Department of Health and Human Services, Health Care Financing Administration, "State Medicaid Manual: Part 6 - Payment for Services," Transmittal No. 37 (November 2001).
  - First DataBank (Alabama Production) Data and NDDF (*National Drug Data File*)<sup>TM</sup> Documentation Manual (Rev. April 2000).
  - FloridaInfusion, Nations Drug, Accessed February 6, 2009 <<http://www.floridainfusion.com/awps.asp?keyword=capoten&searchfield=keyword>>.
  - Medicaid State Drug Utilization Data including "Definitions for State Drug Utilization Data Specifications", Centers for Medicare & Medicaid Services.
  - Medispan Inactive Dates, 2007 Wolters Kluwer Health (Medispan).
  - Red Book Advanced Data and *Red Book*<sup>TM</sup> Drug Products and Pricing Developer's Guide Advanced (January 2008).
  - U.S. Food and Drug Administration, Center for Drug Evaluation and Research, *Approved Drug Products with Therapeutic Equivalence Evaluations*, 11th Edition - 27th Edition.
  - U.S. Food and Drug Administration, Center for Drug Evaluation and Research, *National Drug Code Directory*, <<http://www.fda.gov/cder/ndc/database/>>.

## Exhibit 9

Share of Total Units Reimbursed by Medicaid Nationally for Cefadroxil 500 mg Capsule (GCN 048262)<sup>1</sup>  
**FUL: \$3.0789, Effective 01/22/02 to 03/10/03, Set Using a Package Size of 50 and Data Current as of April 2001<sup>2</sup>**  
**2000Q1 - 2002Q4**

"TE Only" Lower Than Candidates<sup>3</sup>  
 "TE&PS" Matching Candidates<sup>3</sup>

Implied FUL <sup>4</sup>	Published WAC <sup>5</sup>	Package Size <sup>6</sup>	NDC	Red Book Company Name <sup>7</sup>	(Percent)											
					2000q1	2000q2	2000q3	2000q4	2001q1	2001q2	2001q3	2001q4	2002q1	2002q2	2002q3	2002q4
(a)	(b)	(c)	(d)	(e)	(f)	(g)	(h)	(i)	(j)	(k)	(l)	(m)	(n)	(o)	(p)	(q)
		20	00087078407	Bristol-Myers Squibb US Md Grp	0.1 %	0.1 %	0.1 %	0.1 %	0.0 %	0.0 %	0.1 %	0.0 %	0.0 %	0.0 %	0.0 %	0.0 %
2.2292		24	00172405843	Teva Pharmaceuticals USA	1.4	1.3	1.5	1.5	1.7	1.4	1.4	1.4	1.6	1.4	1.4	1.5
		24	00087078441	Bristol-Myers Squibb US Md Grp*										0.0		
3.0789	2.0526	50	00172405848	Teva Pharmaceuticals USA	6.3	6.2	5.6	5.7	5.7	5.5	5.4	5.8	5.4	6.2	6.5	7.0
	2.2388	50	00555058210	Barr Laboratories, Inc.	0.2	1.6	6.0	7.2	7.3	8.3	8.2	8.6	7.9	8.2	8.6	8.2
	2.2388	50	63304058250	Ranbaxy Pharmaceuticals, Inc.	0.1	0.2	0.3	0.5	0.6	0.7	0.9	0.9	1.1	0.9	0.8	0.8
	2.5760	50	59772727103	Sandoz	15.7	16.7	9.7	8.5	8.3	8.4	8.4	8.2	7.6	7.0	6.7	6.1
	3.9286	50	00087078446	Warner Chilcott Laboratories	0.6	0.5	0.4	0.4	0.5	0.5	0.5	0.5	0.4	0.3	0.3	0.3
		50	00015727150	Bristol-Myers Squibb US Md Grp												
		50	00904787851	Major Pharmaceuticals												
1.2749	0.8499	100	00904787860	Major Pharmaceuticals*	0.2	0.3	0.3	0.2	0.1	0.1	0.2	0.3	0.2	0.3	0.3	0.3
2.9325	1.9550	100	00172405860	Teva Pharmaceuticals USA	39.0	35.6	37.6	37.0	37.7	37.8	37.6	38.4	37.4	41.2	42.5	43.8
	2.1233	100	00555058202	Barr Laboratories, Inc.	2.4	3.2	3.3	3.2	3.3	3.1	3.3	3.5	3.6	3.9	3.8	3.6
	2.1233	100	63304058201	Ranbaxy Pharmaceuticals, Inc.	2.1	2.5	3.2	4.1	4.0	4.4	5.3	5.0	5.7	5.2	4.5	5.6
	2.4400	100	59772727104	Geneva Pharmaceuticals, Inc.	28.8	29.2	29.2	28.8	28.1	27.7	27.1	26.2	26.5	24.5	23.9	22.3
		100	00087078442	Bristol-Myers Squibb US Md Grp	1.4	0.7	0.7	0.6	0.5	0.5	0.4	0.2	1.2	0.2	0.2	0.1
		100	00087078444	Bristol-Myers Squibb US Md Grp	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
		100	00182189601	Ivax Pharmaceuticals, Inc.*	0.0											
		100	00536021901	Rugby Laboratories, Inc.	0.2	0.2	0.1	0.1	0.1	0.1	0.1	0.0	0.1			
		100	0090454060	Major Pharmaceuticals	0.0	0.0	0.1	0.1	0.1	0.1	0.0			0.0	0.0	0.0
		100	59772727107	Geneva Pharmaceuticals, Inc.	1.6	1.8	1.7	1.8	1.8	1.5	1.2	1.0	1.1	0.6	0.4	0.4
		500	00172405870	Ivax Pharmaceuticals, Inc.	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.1	0.0	0.0	0.0
			Total:		100.0 %	100.0 %	100.0 %	100.0 %	100.0 %	100.0 %	100.0 %	100.0 %	100.0 %	100.0 %	100.0 %	100.0 %

Notes: - Shares are displayed rounded to one decimal. Hence, values of "0.0" correspond to NDCs for which the quarterly share was less than 0.05 percent. Missing values correspond to quarters for which Medicaid reimbursement was not reported in the CMS data for the specified NDC.

- Table includes all NDCs identified as belonging to the GCN (see Note 1) for which Medicaid reimbursement was reported by CMS for the selected period.

<sup>1</sup> Shares are calculated as the total units reimbursed nationally by Medicaid for the specified NDC relative to the total units reimbursed across all NDCs identified as belonging to the GCN. NDCs identified as belonging to the GCN include: (1) products explicitly identified by the First DataBank ("FDB") variable "GCN Sequence Number" as belonging to the GCN; (2) any similarly described products (based on name, strength, and dosage form) not listed in FDB that appear in Medispan or Red Book and not exclusively in another GCN in FDB at the NDC-9 level. Finally, following a review of online sources for NDCs that do not appear in FDB at the NDC-11 or NDC-9 level (355 NDCs in total, across all 9 GCNs), seven NDCs were dropped from the analysis (52493084701, 52493084717, 54977069501, 54977070601, 57362011601, 63874074917, and 51655027924), as either they were described as albuterol inhaler refills and not as albuterol inhalers or discrepancies in their descriptions were resolved such that they were confirmed to be outside the GCN.

<sup>2</sup> The FUL, the month during which data used to set the FUL was current (i.e., the "current month"), the package size used to set the FUL, and the beginning of the FUL effective period are based on data reported in the CMS transmittals. The end of the FUL effective period is based on data reported in FDB and Red Book.

<sup>3</sup> Lower than and matching candidates are based on published compendia prices tabulated in Exhibits 3 and 5, respectively, of the Report of Dr. Sumanth Addanki. Selected candidates correspond to the narrowest set of requirements (i.e., therapeutic equivalence and package size) for which published compendia prices were identified in Exhibits 3 and 5. Records for which multiple NDCs are identified correspond to instances where lower than or matching candidates with reimbursement during the relevant period are reported for two or more NDCs corresponding to the same product, as occurs when the NDC for a product changes.

<sup>4</sup> The implied FUL is calculated by multiplying the published compendia price by 1.5 and rounding to four decimals. The implied FUL is only populated for NDCs identified as matching or lower than candidates.

<sup>5</sup> The "Published WAC", which is displayed rounded to four decimals, is based on compendia WACs reported by Medispan, FDB, and Red Book. Unless noted otherwise, WACs must be active (i.e., the price has not been deactivated by obsolescence, a subsequent price posting, or otherwise) for the entire current month. NDCs with multiple WACs listed correspond to products for which different WACs were reported by the compendia. NDCs with a missing WAC correspond to products for which

**Exhibit 9**

**Share of Total Units Reimbursed by Medicaid Nationally for Cefadroxil 500 mg Capsule (GCN 048262)<sup>1</sup>**  
**FUL: \$3.0789, Effective 01/22/02 to 03/10/03, Set Using a Package Size of 50 and Data Current as of April 2001<sup>2</sup>**  
**2000Q1 - 2002Q4**

there was no active WAC at any point during the current month. Obsolescence, generally, is determined with reference to the FDB "Obsolete Date", the FDB "HCFA Termination Date", the Medispan "Inactive Date", and the Red Book "NDC Discontinuation Date" (collectively, the "end dates"). WACs are only analyzed during the period prior to the earliest of the four end dates. However, any postings on or after the earliest end date are treated as a reactivation of the NDC and such postings are analyzed until the next end date. Postings after the second, third, or fourth end date are treated in the same manner. Similarly, the Red Book "Reactivation Date" can reactivate the most recent set of active prices for an NDC, assuming the date falls on or after the discontinuation date and the NDC is not already currently active. Finally, 33 NDCs among all nine GCNs, for which the FDB Obsolete Date exhibited stark inconsistencies across annual files, were examined separately, using price posting activity and CMS reimbursement.

<sup>6</sup> The package size is based on the FDB variable "Package Size". If unavailable, the package size is based on the most common value observed across the Medispan implied package size (the mean ratio between the package and unit prices, rounded to one decimal) and the Red Book variables "Total Quantity - Actual" and "Standard Quantity - Actual".

<sup>7</sup> Company names with an asterisk correspond to NDCs for which Red Book data are unavailable. In such instances the company name is based on NDCs with the same labeler code.

- Sources:
- American Medical Association, *AMA Downloadable Resource Table: Asthma , ASTHMA* Version 3.0 July 2007, <[http://www.ama-assn.org/ama1/pub/upload/mm/370/astcodingspecs307\\_7.xls](http://www.ama-assn.org/ama1/pub/upload/mm/370/astcodingspecs307_7.xls)>.
  - "Comprehensive Price History File," 2007 Wolters Kluwer Health (Medispan).
  - Department of Health and Human Services, Health Care Financing Administration, "State Medicaid Manual: Part 6 - Payment for Services," Transmittal No. 37 (November 2001).
  - First DataBank (Alabama Production) Data and *NDDF (National Drug Data File)TM Documentation Manual* (Rev. April 2000).
  - FloridaInfusion, Nations Drug, Accessed February 6, 2009 <<http://www.floridainfusion.com/awps.asp?keyword=capoten&searchfield=keyword>>.
  - Medicaid State Drug Utilization Data including "Definitions for State Drug Utilization Data Specifications", Centers for Medicare & Medicaid Services.
  - Medispan Inactive Dates, 2007 Wolters Kluwer Health (Medispan).
  - Red Book Advanced Data and *Red BookTM Drug Products and Pricing Developer's Guide Advanced* (January 2008).
  - U.S. Food and Drug Administration, Center for Drug Evaluation and Research, *Approved Drug Products with Therapeutic Equivalence Evaluations*, 11th Edition - 27th Edition.
  - U.S. Food and Drug Administration, Center for Drug Evaluation and Research, *National Drug Code Directory*, <<http://www.fda.gov/cder/ndc/database/>>.

## Exhibit 10

Share of Total Units Reimbursed by Medicaid Nationally for Albuterol Sulfate 0.083% Solution (GCN 005039)<sup>1</sup>  
 FUL: \$0.1450, Effective 01/22/02 to 05/07/05, Set Using a Package Size of 3 and Data Current as of April 2001<sup>2</sup>  
 2000q1 - 2002q4

Implied FUL <sup>4</sup>	Published WAC <sup>5</sup>		Package Size <sup>6</sup>	NDC	Red Book Company Name <sup>7</sup>	(Percent)														
	(a)	(b)				(f)	(g)	(h)	(i)	(j)	(k)	(l)	(m)	(n)	(o)	(p)	(q)			
0.1150	0.0767; 0.1067	3	50383074225	Hi-Tech Pharmacal Co., Inc.	0.3	0.3	0.3	0.2	0.3	0.6	0.6	0.5	0.4	0.3	0.2	0.2	0.2			
0.1154	0.0769	3	60432009406	Morton Grove Pharm., Inc.	%	%	%	0.0 %	0.0 %	0.0 %	0.0 %	0.4 %	0.5 %	0.4 %	0.4 %	0.4 %	0.4 %			
0.1200	0.0800	3	49502069703	Dey, L.P.	27.4	28.8	27.8	26.3	27.2	27.4	27.1	24.9	24.7	24.9	25.9	25.8				
0.1200	0.0800	3	49502069733	Dey, L.P.	2.0	2.0	1.9	1.9	1.8	1.9	2.1	2.0	1.9	2.1	2.8	2.9				
0.1200	0.0800	3	49502069760	Dey, L.P.	11.4	12.4	11.8	11.4	11.9	12.1	12.3	11.6	11.8	11.8	11.3	10.8				
	0.0833	<sup>8</sup> 3	66794000130	RxElite Holdings, Inc.										0.0	0.1	0.2				
	0.0833	<sup>8</sup> 3	66794000160	RxElite Holdings, Inc.										0.0	0.5	1.4				
0.1329	0.0886	3	00472083160	Actavis Mid Atlantic LLC	0.0	0.1	0.2	0.2	2.2	4.6	6.4	7.9	8.4	9.0	8.6	9.1				
0.1337	0.0891	3	00172640549	Teva Pharmaceuticals USA	0.0	0.1	0.3	0.3	0.4	0.5	0.7	1.0	1.4	1.9	2.3	2.7				
0.1350	0.0900	3	00172640544	Teva Pharmaceuticals USA	0.0	0.2	3.1	4.9	5.3	5.0	5.4	6.2	6.2	6.4	6.7	8.0				
0.1400	0.0933	3	00472083130	Actavis Mid Atlantic LLC	0.5	0.6	0.7	0.6	0.5	0.6	0.6	0.5	0.5	0.5	0.7	0.6				
0.1450	0.0967	3	00472083123	Actavis Mid Atlantic LLC	2.0	1.8	1.9	2.6	3.0	3.8	4.3	5.0	5.0	4.7	4.3	4.4				
0.1252; 0.2953		3	00904773117	Major Pharmaceuticals	0.1	0.1	0.2	0.1	0.2	0.3	0.2	0.1	0.1	0.1	0.1	0.1	0.1	0.1		
0.1500		3	00487950103	Nephron Pharmaceuticals Corp.	1.2	1.2	0.5	0.5	0.7	0.9	0.8	0.7	0.6	0.6	0.1	0.1	0.0			
0.1500		3	00487950125	Nephron Pharmaceuticals Corp.																
0.1500		3	00487950160	Nephron Pharmaceuticals Corp.	1.4	1.8	2.3	2.0	2.2	2.5	2.7	2.1	1.9	2.6	2.6	2.2				
0.3300		3	59930150006	Warrick Pharmaceuticals*	5.4	5.0	5.5	5.3	5.5	5.1	4.9	5.0	5.0	5.0	5.0	5.0	3.5			
0.3300		3	59930150008	Warrick Pharmaceuticals*	46.6	44.1	42.2	42.2	37.6	33.6	30.9	30.9	30.5	29.4	27.5	21.4				
0.5424		3	00085020901	Schering Corporation*	0.7	0.7	0.7	0.6	0.5	0.5	0.5	0.4	0.3	0.3	0.2	0.1	0.0			
		3	00054806311	Roxane Laboratories, Inc.								0.1	0.1	0.2	0.1	0.1	0.1	0.1		
		3	00054806313	Roxane Laboratories, Inc.							0.0	0.0	0.1	0.1	0.1	0.2	0.1	0.2	0.1	
		3	00054806321	Roxane Laboratories, Inc.							0.0	0.1	0.2	0.1	0.1	0.2	0.1	0.2	0.2	
		3	00085180601	Schering Corporation														0.0		
		3	00173041900	Allen & Hanburys	0.1	0.1	0.1	0.1	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	
		3	00182801024	Ivax Pharmaceuticals, Inc.	0.4	0.3	0.3	0.3	0.2	0.1	0.1	0.1	0.1	0.0	0.0	0.0	0.0	0.0	0.0	
		3	00182801026	Ivax Pharmaceuticals, Inc.	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	
		3	00186149104	AstraZeneca LP	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	
		3	00186149117	AstraZeneca LP	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	
		3	00487950101	Nephron Pharmaceuticals Corp.											0.0	0.0	0.0			
		3	00536267704	Rugby Laboratories, Inc.	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	
		3	00603100540	Qualitest Pharmaceuticals	0.2	0.1	0.1	0.1	0.1	0.1	0.1	0.1	0.1	0.1	0.1	0.1	0.1	0.1	0.1	0.1
		3	00677152272	United Research Labs, Inc.	0.1	0.0	0.1	0.1	0.0	0.0	0.1	0.1	0.1	0.1	0.1	0.1	0.1	0.1	0.0	0.0
		3	00781915093	Geneva Pharmaceuticals, Inc.	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0		
		3	38245066917	Copley Pharmaceutical, Inc.	0.0				0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	
		3	53014007525	Celtech Pharmaceuticals, Inc.	0.2	0.1	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	
		3	53014007560	Celtech Pharmaceuticals, Inc.	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	
		3	59930151701	Warrick Pharmaceuticals											0.1	5.0				
		3	59930151702	Warrick Pharmaceuticals												0.0		0.0		
		3	65271000205	Aslung Pharmaceutical, L.P.										0.0	0.1	0.1				
		3	65271000206	Aslung Pharmaceutical, L.P.										0.0	0.0	0.1				
		3	66794000125	RxElite Holdings, Inc.										0.0	0.0	0.7				
Total:					100.0 %	100.0 %	100.0 %	100.0 %	100.0 %	100.0 %	100.0 %	100.0 %	100.0 %	100.0 %	100.0 %	100.0 %	100.0 %	100.0 %		

**Exhibit 10**

**Share of Total Units Reimbursed by Medicaid Nationally for Albuterol Sulfate 0.083% Solution (GCN 005039)<sup>1</sup>**  
**FUL: \$0.1450, Effective 01/22/02 to 05/07/05, Set Using a Package Size of 3 and Data Current as of April 2001<sup>2</sup>**  
**2000q1 - 2002q4**

Notes: - Shares are displayed rounded to one decimal. Hence, values of "0.0" correspond to NDCs for which the quarterly share was less than 0.05 percent. Missing values correspond to quarters for which Medicaid reimbursement was not reported in the CMS data for the specified NDC.

- Table includes all NDCs identified as belonging to the GCN (see Note 1) for which Medicaid reimbursement was reported by CMS for the selected period.

<sup>1</sup> Shares are calculated as the total units reimbursed nationally by Medicaid for the specified NDC relative to the total units reimbursed across all NDCs identified as belonging to the GCN. NDCs identified as belonging to the GCN include: (1) products explicitly identified by the First DataBank ("FDB") variable "GCN Sequence Number" as belonging to the GCN; (2) any similarly described products (based on name, strength, and dosage form) not listed in FDB that appear in Medispan or Red Book and not exclusively in another GCN in FDB at the NDC-9 level. Finally, following a review of online sources for NDCs that do not appear in FDB at the NDC-11 or NDC-9 level (355 NDCs in total, across all 9 GCNs), seven NDCs were dropped from the analysis (52493084701, 52493084717, 54977069501, 54977070601, 57362011601, 63874074917, and 51655027924), as either they were described as albuterol inhaler refills and not as albuterol inhalers or discrepancies in their descriptions were resolved such that they were confirmed to be outside the GCN.

<sup>2</sup> The FUL, the month during which data used to set the FUL was current (i.e., the "current month"), the package size used to set the FUL, and the beginning of the FUL effective period are based on data reported in the CMS transmittals. The end of the FUL effective period is based on data reported in FDB and Red Book.

<sup>3</sup> Lower and matching candidates are based on published compendia prices tabulated in Exhibits 3 and 5, respectively, of the Report of Dr. Sumanth Addanki. Selected candidates correspond to the narrowest set of requirements (i.e., therapeutical equivalence and package size) for which published compendia prices were identified in Exhibits 3 and 5. Records for which multiple NDCs are identified correspond to instances where lower than or matching candidates with reimbursement during the relevant period are reported for two or more NDCs corresponding to the same product, as occurs when the NDC for a product changes.

<sup>4</sup> The implied FUL is calculated by multiplying the published compendia price by 1.5 and rounding to four decimals. The implied FUL is only populated for NDCs identified as matching or lower than candidates.

<sup>5</sup> The "Published WAC", which is displayed rounded to four decimals, is based on compendia WACs reported by Medispan, FDB, and Red Book. Unless noted otherwise, WACs must be active (i.e., the price has not been deactivated by obsolescence, a subsequent price posting, or otherwise) for the entire current month. NDCs with multiple WACs listed correspond to products for which different WACs were reported by the compendia. NDCs with a missing WAC correspond to products for which there was no active WAC at any point during the current month. Obsolescence, generally, is determined with reference to the FDB "Obsolete Date", the FDB "HCFA Termination Date", the Medispan "Inactive Date", and the Red Book "NDC Discontinuation Date" (collectively, the "end dates"). WACs are only analyzed during the period prior to the earliest of the four end dates. However, any postings on or after the earliest end date are treated as a reactivation of the NDC and such postings are analyzed until the next end date. Postings after the second, third, or fourth end date are treated in the same manner. Similarly, the Red Book "Reactivation Date" can reactivate the most recent set of active prices for an NDC, assuming the date falls on or after the discontinuation date and the NDC is not already currently active. Finally, 33 NDCs among all nine GCNs, for which the FDB Obsolete Date exhibited stark inconsistencies across annual files, were examined separately, using price posting activity and CMS reimbursement.

<sup>6</sup> The package size is based on the FDB variable "Package Size". If unavailable, the package size is based on the most common value observed across the Medispan implied package size (the mean ratio between the package and unit prices, rounded to one decimal) and the Red Book variables "Total Quantity - Actual" and "Standard Quantity - Actual".

<sup>7</sup> Company names with an asterisk correspond to NDCs for which Red Book data are unavailable. In such instances the company name is based on NDCs with the same labeler code.

<sup>8</sup> The specified WAC was only active for part of the current month, as it was posted by FDB on April 15, 2001.

Sources: - American Medical Association, *AMA Downloadable Resource Table: Asthma*, ASTHMA Version 3.0 July 2007, <[http://www.ama-assn.org/ama1/pub/upload/mm/370/astcodingspecs307\\_7.xls](http://www.ama-assn.org/ama1/pub/upload/mm/370/astcodingspecs307_7.xls)>.  
- "Comprehensive Price History File," 2007 Wolters Kluwer Health (Medispan).  
- Department of Health and Human Services, Health Care Financing Administration, "State Medicaid Manual: Part 6 - Payment for Services," Transmittal No. 37 (November 2001).  
- First DataBank (Alabama Production) Data and NDDF (*National Drug Data File*)<sup>TM</sup> Documentation Manual (Rev. April 2000).  
- FloridaInfusion, Nations Drug, Accessed February 6, 2009 <<http://www.floridainfusion.com/awps.asp?keyword=capoten&searchfield=keyword>>.  
- Medicaid State Drug Utilization Data including "Definitions for State Drug Utilization Data Specifications", Centers for Medicare & Medicaid Services.  
- Medispan Inactive Dates, 2007 Wolters Kluwer Health (Medispan).  
- Red Book Advanced Data and *Red Book*<sup>TM</sup> *Drug Products and Pricing Developer's Guide Advanced* (January 2008).  
- U.S. Food and Drug Administration, Center for Drug Evaluation and Research, *Approved Drug Products with Therapeutic Equivalence Evaluations*, 11th Edition - 27th Edition.  
- U.S. Food and Drug Administration, Center for Drug Evaluation and Research, *National Drug Code Directory*, <<http://www.fda.gov/cder/ndc/database/>>.

## Exhibit 11

Share of Total Units Reimbursed by Medicaid Nationally for Albuterol 90 mcg Inhaler (GCN 005037)<sup>1</sup>  
**FUL: \$0.4394, Effective 10/01/97 to 12/06/00, Set Using a Package Size of 17 and Data Current as of June 1997<sup>2,3</sup>**  
 1996q1 - 1998q4

"TE&PS" Lower Than Candidates<sup>4</sup>  
 "PS Only" Matching Candidates<sup>4</sup>

Implied FUL <sup>5</sup>	Published WAC <sup>6</sup>	Package Size <sup>7</sup>	NDC	Red Book Company Name <sup>8</sup>	(Percent)												
					1996q1	1996q2	1996q3	1996q4	1997q1	1997q2	1997q3	1997q4	1998q1	1998q2	1998q3	1998q4	
(a)	(b)	(c)	(d)	(e)	(f)	(g)	(h)	(i)	(j)	(k)	(l)	(m)	(n)	(o)	(p)	(q)	
1.7853	6.8	00173046300	Glaxo SmithKline Pharm.	0.0 %	0.0 %	0.0 %	0.0 %	0.0 %	0.0 %	0.0 %	0.0 %	0.0 %	0.0 %	0.0 %	0.0 %	0.0 %	
0.2100; 0.7529	17.0	5255059417	Martec Pharmaceutical, Inc.	0.0	0.2	0.4	0.5	0.6	0.7	0.7	0.8	0.7	0.9	0.6	0.7		
0.3309	0.2206; 0.3265	17.0	00172439018	Teva Pharmaceuticals USA	7.0	19.8	23.7	23.8	23.3	24.0	22.5	18.7	14.6	14.2	13.7	13.0	
0.4394	0.2929; 0.9453	17.0	00603100475	Qualitest Pharmaceuticals	0.2	0.6	0.8	0.9	1.0	0.8	0.8	0.9	0.7	0.8	0.7	0.8	
	0.3947	17.0	00781750287	Geneva Pharmaceuticals, Inc.	0.0	0.1	0.2	0.2	0.2	0.2	0.3	0.6	0.4	0.4	0.3	0.3	
	0.4118	17.0	00364263298	Schein Pharmaceutical, Inc.	0.3	1.1	2.5	1.4	1.3	1.2	1.1	1.1	0.9	0.9	0.9	0.9	
	0.4706	17.0	50111080131	Pliva, Inc.			0.0	0.9	1.4	1.8	2.8	4.0	4.3	3.5	2.2	2.5	
	0.5047	17.0	00536041612	Rugby Laboratories, Inc.	0.4	1.1	1.1	0.9	0.9	0.8	1.0	0.8	0.7	0.7	0.6	0.6	
	0.5047	17.0	00536121612	Rugby Laboratories, Inc.		0.0	0.1	0.1	0.1	0.2	0.2	0.1	0.1	0.1	0.1	0.1	
	0.7588	17.0	49502030317	Dey, L.P.*	1.0	4.5	6.1	6.5	6.7	7.6	7.4	7.1	7.0	7.8	7.3	6.6	
	0.8018	17.0	00677154970	United Research Labs, Inc.	0.0	0.0	0.0	0.1	0.1	0.1	0.1	0.1	0.1	0.1	0.2	0.1	
	0.8971	17.0	55953005153	Novopharm USA Inc.	0.1	1.4	2.9	4.4	4.3	6.5	8.3	8.0	6.7	5.7	5.3	5.0	
0.9394; 1.0153	17.0	00904507834	Major Pharmaceuticals	0.1	0.4	0.4	0.6	0.5	0.5	0.5	0.6	0.5	0.7	0.6	0.6	0.6	
0.9447	17.0	59930156001	Warrick Pharmaceuticals	4.0	14.7	20.6	27.7	31.5	28.5	30.0	32.9	38.4	38.2	42.5	46.2		
1.0082	17.0	59772617502	Apothecon Products			0.0	0.5	1.7	3.0	4.5	7.1	8.9	10.8	12.2	11.2		
1.1253	17.0	00047299711	Warner Chilcott, Gen Prods Div				0.1	0.3	0.7	1.0	1.3	1.5	1.5	1.4	1.5		
1.2988	17.0	00085061402	Schering Corporation	56.3	33.3	24.3	18.0	14.9	13.4	10.3	8.1	6.7	6.6	6.2	5.3		
1.2988	17.0	00173032188	Glaxo SmithKline Pharm.	30.1	21.6	15.6	12.2	10.0	8.8	7.6	5.4	4.2	4.4	4.0	3.8		
	17.0	00472126478	Alpharma USPD									1.5	2.7	2.2	1.0	0.8	
	17.0	00839760807	Moore, H.L. Drug Exchange Inc.		0.2	1.0	1.2	1.3	1.3	1.2	1.0	0.8	0.7	0.5	0.1	0.1	
			Total:		100.0 %	100.0 %	100.0 %	100.0 %	100.0 %	100.0 %	100.0 %	100.0 %	100.0 %	100.0 %	100.0 %	100.0 %	100.0 %

Notes: - Shares are displayed rounded to one decimal. Hence, values of "0.0" correspond to NDCs for which the quarterly share was less than 0.05 percent. Missing values correspond to quarters for which Medicaid reimbursement was not reported in the CMS data for the specified NDC.

- Table includes all NDCs identified as belonging to the GCN (see Note 1) for which Medicaid reimbursement was reported by CMS for the selected period.

<sup>1</sup> Shares are calculated as the total units reimbursed nationally by Medicaid for the specified NDC relative to the total units reimbursed across all NDCs identified as belonging to the GCN. NDCs identified as belonging to the GCN include: (1) products explicitly identified by the First DataBank ("FDB") variable "GCN Sequence Number" as belonging to the GCN; (2) any similarly described products (based on name, strength, and dosage form) not listed in FDB that appear in Medispan or Red Book and not exclusively in another GCN in FDB at the NDC-9 level. Finally, following a review of online sources for NDCs that do not appear in FDB at the NDC-11 or NDC-9 level (355 NDCs in total, across all 9 GCNs), seven NDCs were dropped from the analysis (52493084701, 52493084717, 54977069501, 54977070601, 57362011601, 63874074917, and 51655027924), as either they were described as albuterol inhaler refills and not as albuterol inhalers or discrepancies in their descriptions were resolved such that they were confirmed to be outside the GCN.

<sup>2</sup> The FUL, the month during which data used to set the FUL was current (i.e., the "current month"), the package size used to set the FUL, and the beginning of the FUL effective period are based on data reported in the CMS transmittals. The end of the FUL effective period is based on data reported in FDB and Red Book.

<sup>3</sup> While the FUL was reported in a later transmittal, the month during which data used to set the FUL was current is based on an earlier transmittal that reported the FUL for the albuterol inhaler refill, as the FULs for the refill and the inhaler have the same value and appear to have been posted in FDB simultaneously at a time consistent with the earlier transmittal.

<sup>4</sup> Lower than and matching candidates are based on published compendia prices tabulated in Exhibits 3 and 5, respectively, of the Report of Dr. Sumanth Addanki. Selected candidates correspond to the narrowest set of requirements (i.e., therapeutic equivalence and package size) for which published compendia prices were identified in Exhibits 3 and 5. Records for which multiple NDCs are identified correspond to instances where lower than or matching candidates with reimbursement during the relevant period are reported for two or more NDCs corresponding to the same product, as occurs when the NDC for a product changes.

<sup>5</sup> The implied FUL is calculated by multiplying the published compendia price by 1.5 and rounding to four decimals. The implied FUL is only populated for NDCs identified as matching or lower than candidates.

<sup>6</sup> The "Published WAC", which is displayed rounded to four decimals, is based on compendia WACs reported by Medispan, FDB, and Red Book. Unless noted otherwise, WACs must be active (i.e., the price has not been deactivated by obsolescence, a subsequent price posting, or otherwise) for the entire current month. NDCs with multiple WACs listed correspond to products for which different WACs were reported by the compendia. NDCs with a missing WAC correspond to products for which there was no active WAC at any point during the current month. Obsolescence, generally, is determined with reference to the FDB "Obsolete Date", the FDB "HCFA Termination Date", the Medispan "Inactive Date", and the Red Book "NDC

**Exhibit 11**

**Share of Total Units Reimbursed by Medicaid Nationally for Albuterol 90 mcg Inhaler (GCN 005037)<sup>1</sup>**  
**FUL: \$0.4394, Effective 10/01/97 to 12/06/00, Set Using a Package Size of 17 and Data Current as of June 1997<sup>2,3</sup>**  
**1996q1 - 1998q4**

Discontinuation Date" (collectively, the "end dates"). WACs are only analyzed during the period prior to the earliest of the four end dates. However, any postings on or after the earliest end date are treated as a reactivation of the NDC and such postings are analyzed until the next end date. Postings after the second, third, or fourth end date are treated in the same manner. Similarly, the Red Book "Reactivation Date" can reactivate the most recent set of active prices for an NDC, assuming the date falls on or after the discontinuation date and the NDC is not already currently active. Finally, 33 NDCs among all nine GCNs, for which the FDB Obsolete Date exhibited stark inconsistencies across annual files, were examined separately, using price posting activity and CMS reimbursement.

<sup>7</sup> The package size is based on the FDB variable "Package Size". If unavailable, the package size is based on the most common value observed across the Medispan implied package size (the mean ratio between the package and unit prices, rounded to one decimal) and the Red Book variables "Total Quantity - Actual" and "Standard Quantity - Actual".

<sup>8</sup> Company names with an asterisk correspond to NDCs for which Red Book data are unavailable. In such instances the company name is based on NDCs with the same labeler code.

- Sources: - American Medical Association, *AMA Downloadable Resource Table: Asthma*, ASTHMA Version 3.0 July 2007, <[http://www.ama-assn.org/ama1/pub/upload/mm/370/astcodingspecs307\\_7.xls](http://www.ama-assn.org/ama1/pub/upload/mm/370/astcodingspecs307_7.xls)>.  
- "Comprehensive Price History File," 2007 Wolters Kluwer Health (Medispan).  
- Department of Health and Human Services, Health Care Financing Administration, "State Medicaid Manual: Part 6 - Payment for Services," Transmittal Nos. 34 (July 1997) and 35 (July 1998).  
- First DataBank (Alabama Production) Data and *NDDF (National Drug Data File)TM Documentation Manual* (Rev. April 2000).  
- FloridaInfusion, Nations Drug, Accessed February 6, 2009 <<http://www.floridainfusion.com/awps.asp?keyword=capoten&searchfield=keyword>>.  
- Medicaid State Drug Utilization Data including "Definitions for State Drug Utilization Data Specifications", Centers for Medicare & Medicaid Services.  
- Medispan Inactive Dates, 2007 Wolters Kluwer Health (Medispan).  
- Red Book Advanced Data and *Red BookTM Drug Products and Pricing Developer's Guide Advanced* (January 2008).  
- U.S. Food and Drug Administration, Center for Drug Evaluation and Research, *Approved Drug Products with Therapeutic Equivalence Evaluations*, 11th Edition - 27th Edition.  
- U.S. Food and Drug Administration, Center for Drug Evaluation and Research, *National Drug Code Directory*, <<http://www.fda.gov/cder/ndc/database/>>.